

AD _____

Award Number: DAMD17-99-1-9005

TITLE: African American Men in the PLCO Trial: Developing and
Testing Methods to Increase Retention

PRINCIPAL INVESTIGATOR: Marvella E. Ford, Ph.D.

CONTRACTING ORGANIZATION: Henry Ford Health Sciences Center
Detroit, Michigan 48202

REPORT DATE: February 2000

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE February 2000	3. REPORT TYPE AND DATES COVERED Annual (4 Jan 99 - 3 Jan 00)	
4. TITLE AND SUBTITLE African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention			5. FUNDING NUMBERS DAMD17-99-1-9005	
6. AUTHOR(S) Marvella E. Ford, Ph.D.			8. PERFORMING ORGANIZATION REPORT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry Ford Health Sciences Center Detroit, Michigan 48202 E-MAIL:				
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) The specific aims of this randomized trial are to evaluate the efficacy of an innovative intervention in retaining African American men in the screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial at the Henry Ford Health System site, and to develop a culturally appropriate measurement instrument to assess perceptions of cancer screening. The study population consists of African American men aged 55 and older living in southeastern Michigan. Information related to community resources is shared with the study participants. Thus, competing needs that may prevent them from adhering to their PLCO screening tests are addressed. No statistically significant differences were found in education or age between the intervention group (n=301) and the control group (n=300). In terms of the measurement instrument, a literature search on African Americans' perceptions of cancer screening was conducted, potential survey items were placed into a theoretical framework, and a focus group was held. An abstract documenting the design of the study was submitted for presentation at the 2000 American Association for Cancer Research Conference. The findings of this study can be used to help African American men benefit from the positive aspects of participation in prostate cancer research.				
14. SUBJECT TERMS Prostate Cancer, African American Men, Clinical Trials, Retention			15. NUMBER OF PAGES 312	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

20010301 096

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

N/A Where copyrighted material is quoted, permission has been obtained to use such material.

N/A Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

N/A Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

N/A For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

<u>Marvella E. Ford</u>	2-1-00
PI - Signature	Date

Table of Contents

Front Cover	1
Standard Form 298 Documentation Page	2
Foreword	3
Table of Contents	4
Introduction	5
Body	6
Statement of Work	6
Task 1 (a): Hire and train the case manager/retention coordinator and train the other study staff	7
Task 1 (b): Assign HFHS PLCO Cancer Screening Trial participants in the screening arm a socioeconomic status code and then assign them to the case manager/retention coordinator intervention group or to a control group	7
Figure 1	8
Task 1 (c): Implement the retention intervention	9
Task 1 (d): Conduct preliminary statistical analyses of the retention intervention	11
Table 1	12
Table 2	12
Table 3	13
Table 4	14
Table 5	15
Task 1 (e)	15
Task 2 (a & b)	15
Task 2 (c)	20
Task 2 (d)	27
Figure 2 - Methods Used in the Focus Group	29
Task 2 (e) - (i)	31
Key Research Accomplishments	32
Reportable Outcomes	32
Conclusions	33
References	36
Appendix	

INTRODUCTION

Subject And Purpose Of The Research

The objective of this feasibility study is to identify innovative methods for increasing the retention of African American men in prostate cancer screening trials. Retention, while important for all groups, is especially critical for African American men, given their often low representation in clinical trials. The specific aims are to evaluate the efficacy of a retention intervention in retaining African American men in the screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial at the Henry Ford Health System site, and to develop a culturally appropriate measurement instrument to assess perceptions of screening for these cancers among older African American men.

Scope Of The Research

The study population consists of African American men aged 55 and older living in the Detroit area. Blocked randomization methods were used to assign the men to the retention intervention or control group. A retention coordinator provides intense follow-up to the men in the intervention group and guides them through the PLCO Trial screening processes. Socioeconomic status will be used as a covariate in later analyses.

It is hypothesized that men in the intervention group will show higher screening adherence rates than men in the control group. An instrument to assess cancer-screening perceptions among older African American men will be developed using focus group techniques. The findings from this study will lay the foundation for randomized trials of the retention intervention (modified if necessary) in large prostate cancer screening or treatment trials involving African American men of different age groups. The psychometric properties of the measurement instrument could be tested for older and younger African American men. The instrument could then be used to help to identify potential study dropouts, who may need more intensive interventions in order to reduce attrition.

The retention study of African American men randomized to the intervention (screening) arm of the PLCO Trial began in June 1999 after five months of planning. In the retention study, 301 men have been randomly assigned to the intervention group and 300 men have been randomly assigned to the control group. The research protocol for the retention study has been approved by the Henry Ford Health System Institutional Review Board (HFHS IRB). An HFHS IRB continuation application was submitted. The HFHS IRB committee reviewed this form in November 1999 and gave continued IRB approval through 2000 (Appendix A).

Retention study staff include Marvella E. Ford, Ph.D., Principal Investigator, Christine Cole Johnson, Ph.D., Co-Investigator, Michelle Jankowski, M.A.S., Statistician, Vernetta Randolph, Retention Coordinator, and Felecia Collins, Secretary. Consultants to the study include G. Marie Swanson, Ph.D. and Sally Vernon, Ph.D. On May 24, 1999 a Consultant Meeting was held with Drs. Swanson and Vernon. The meeting continued on May 25, 1999 with Dr. Vernon. The agenda for this meeting is included in Appendix B.

BODY

Statement of Work

African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention

Task 1. Develop and test the case manager/retention coordinator intervention in the PLCO Cancer Screening Trial

- (a) Hire and train the case manager/retention coordinator and train the other study staff (months 1-4)
- (b) Assign HFHS PLCO Cancer Screening Trial participants in the screening arm a socioeconomic status code and then assign them to the case manager/retention coordinator intervention group or to a control group (month 4)
- (c) Implement the retention intervention (months 5-28)
- (d) Conduct preliminary statistical analyses of the retention intervention (months 8-28)
- (e) Conduct final analyses (months 28-30)

Task 2. Develop a culturally appropriate measurement instrument to assess cancer screening perceptions of African American men

- (a) Conduct a literature search of existing instruments assessing cancer screening knowledge, attitudes, and beliefs among African American men (months 1-7)
- (b) Use the results of the literature search to document the reliability/validity, purpose and conceptual approach of each measurement instrument, and its cultural appropriateness for African American men (months 1-7)
- (c) Use the results of the literature search to develop focus group questions (months 8-12)
- (d) Hold a focus group session to assess participants' perceptions of the developing measurement instrument and to garner ideas for new questions (month 13)
- (e) Based on the focus group results, revise the measurement instrument (months 14-20)
- (f) Hold a focus group session to assess participants' perceptions of the revised measurement instrument (month 21)
- (g) Incorporate participants' suggestions into a further refinement of the instrument (months 22-30)
- (h) Conduct statistical analyses of the pilot study results (months 26-27)
- (i) Revise and refine the final measurement instrument, based on the pilot study results (months 28-30)

Progress related to each task in the Statement of Work is described in the following sections of the annual report.

Task 1 (a): *Hire and train the case manager/retention coordinator and train the other study staff (months 1-4)*

A case manager/retention coordinator was hired and began training in month 1. However, she took another position at the end of month 2. A search was conducted for another case manager/retention coordinator, who was hired and trained in months 4-6.

Task 1 (b): *Assign HFHS PLCO Cancer Screening Trial participants in the screening arm a socioeconomic status code and then assign them to the case manager/retention coordinator intervention group or to a control group (month 4)*

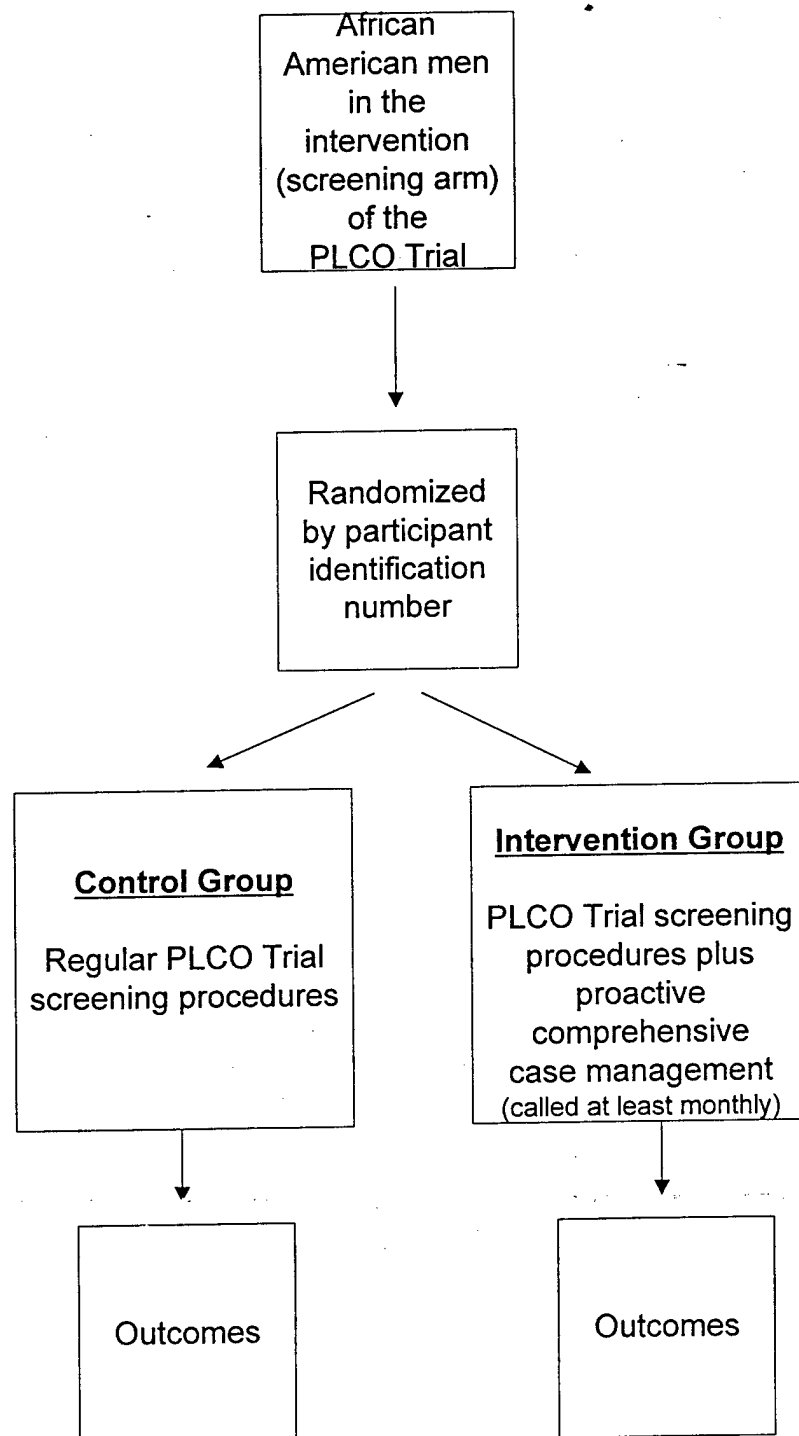
Randomization (Figure 1) and other study procedures took place starting in month 6, once the case manager/retention coordinator was fully trained. Part of the training consisted of contacting a large number of agencies serving community adults, particularly older adults, to develop a resource file of available community resources. These resources are shared with the study participants during the course of the study, as one of the study goals is to serve as an information clearinghouse for participants. In this manner, competing needs of the participants that may function to prevent them from adhering to their PLCO screening tests are addressed by the case manager/retention coordinator. The study procedures are documented in the following paragraphs.

Retention Study Procedures

- 1) A data manager generated a list of all African American males in the PLCO Trial Intervention Arm (n=601).
 - ☐ This list only contained the names of active participants. It did not include people who were being tracked or lost to follow-up, deceased people, or people who have refused all further contact by PLCO staff.
- 2) The statistician on the retention study, Ms. Michelle Jankowski, randomized individuals on the list to Control or Intervention groups.
- 3) The Retention Coordinator, Ms. Vernetta Randolph, generated a list of study participants by Control and Intervention groups.
- 4) The group assignment information was forwarded to PLCO staff and a data manager generated separate Overview Sheets for each participant. The information on the Overview Sheets for each participant includes:
 - ☐ Demographic information
 - ☐ Study identification number
 - ☐ Screening examinations received (*based on study year*)
 - ☐ Telephone number(s) where participants can be reached
- 5) Before the retention study began:
 - a) Ms. Jankowski developed an Access database to record telephone calls and specific interventions for each participant.
 - b) Each participant's status (DOD-I or DOD-C) was inserted into the SMS scheduling notes.
- 6) The retention study participants were pulled from the PLCO Cancer Screening Trial database in July 1999, when the intervention was implemented.

Figure 1

**African American Men in the PLCO Trial:
Developing and Testing Methods to
Increase Retention**



Task 1 (c): *Implement the retention intervention (months 5-28)*

Due to the turnover in the case manager/retention coordinator position, the retention intervention began in July 1999. Retention intervention procedures related to scheduling are described in the paragraphs below. In addition, the investigators developed telephone scripts for each type of telephone contact, for use by the case manager/retention coordinator. These scripts are included in Appendix C. The case manager/retention coordinator was trained in the administering of these scripts during months 4-6. These scripts are tailored based on the following variables: each participant's study year; the types of exams each participant is scheduled to receive each year; and the extent to which each participant adhered to their scheduled screening exams in the previous year. Tailoring the scripts for each study participant allows barriers counseling specific to each individual to be conducted.

- A. Personal Identification (PID) numbers for each participant were printed on a listing generated by the PLCO data manager.
 - These PID numbers were used to generate an Annual Study Update (ASU) that is mailed to participants enrolled in the study.
 - Also from the PID listing, a participant overview form was generated. This form identifies which screening tests are needed.
- B. The PLCO data manager filed the participant overview sheets and contact sheets by (a) study year, (b) randomization date, and (c) alphabetical order.
- C. The PLCO data manager gives Ms. Randolph the retention study participant overview sheets and contact sheets for the retention study participants with an upcoming annual screening examination. Retention study staff use a temporary filing system similar to that described in (B) to store documents on a temporary basis.
- D. Ms. Randolph checks the participant overview sheet to see which study year the person is in (e.g. T0, T1, and etc.) and she identifies whether the person is in the retention study intervention (DOD-I) or retention study control group (DOD-C).
- E. Ms. Randolph stamps the upper right corner of the participant overview sheet using a stamp inscribed DOD-I or DOD-C.
 - DOD-I: Intervention Group. For this group, Ms. Randolph places a call to each participants' home once a month to schedule screening appointments and address any human services needs. (At the start of the project, Ms. Randolph let the participant and his spouse/mate know that she would call the home monthly to talk with the participant.)
 - When establishing contact with the participant, Ms. Randolph asks to speak with the participant's spouse/mate and asks whether she/he has any human services needs.
 - DOD-C: Control Group. For this group, Ms. Randolph only places a call to each participant's home to schedule screening appointments when needed.
 - **Note:** If a DOD-I participant had already received a scheduling call from PLCO at the beginning of the retention study, Ms. Randolph did not call the participant until the next month.
- F. For the DOD-C group participants, Ms. Randolph uses the standard PLCO scheduling script.
- G. For the DOD-I group participants, Ms. Randolph uses the enhanced scheduling script.
- H. Ms. Randolph schedules the appropriate screening appointment(s) using the PLCO scheduling method and stamps/writes DOD-I (Intervention) or DOD-C (Control) on the name line of the schedule form in the right corner.
- I. Ms. Randolph records all interactions with DOD-I participants in an Access database checklist. She enters text summarizing each discussion with each study participant in a Microsoft Word file. This information is updated daily.

- J. At the end of each business day, or prior to 7:30 a.m. of the next business day, Ms. Randolph gives the completed contact forms and overview sheets to the PLCO screening appointment schedulers.
- K. On Tuesdays, the PLCO screening appointment schedulers review all contact forms and overview sheets and once the information has been reviewed, the 'final' sheets are given to the PLCO secretaries, who prepare a typed schedule and add DOD-I and DOD-C to the name line, when appropriate. PLCO office staff instruct PLCO clinic staff to ignore the DOD-I/ DOD-C (across from participants' name) information that is added to the appointment schedule. The PLCO secretaries make a copy of the typed appointment schedule for Ms. Randolph. Ms. Randolph ignores all non-retention study participants when making her reminder calls for scheduled PLCO screening appointments, and therefore only calls retention study participants.
- L. The PLCO secretaries prepare 2 copies of screening appointment reminder letters and send one copy to the participant. Participants are instructed to call the general PLCO number to cancel or reschedule appointments. (*See N*) The other copy is placed in the participant's file along with the contact sheet and overview sheet. This information is filed in the PLCO scheduling office.
- M. The day before each retention study participant's scheduled screening appointment, Ms. Randolph places a reminder call to the retention study participant.
- N. If a retention study participant cancels his appointment during the reminder call, Ms. Randolph notes this information on her typed appointment list and notifies the PLCO screening appointment schedulers of the cancellation.
- O. Cancellations: The PLCO screening appointment schedulers contact the PLCO screening clinics regarding **ALL** cancelled appointments.
 - ☐ Ms. Randolph re-schedules all retention study participant appointments.
 - ☐ When a participant calls the general PLCO number to cancel a screening appointment, the PLCO screening appointment schedulers do not re-schedule the appointment, which is different than the PLCO process. Instead, the PLCO screening appointment schedulers notify Ms. Randolph, who then contacts the retention study participants to re-schedule their annual screening appointments.

Originally, the case manager/retention coordinator was only going to conduct scheduling calls for the participants assigned to the intervention group. However, one of the retention study's co-investigators pointed out the fact that a potential source of bias, "interviewer bias", would be reduced if Ms. Randolph, the retention coordinator, scheduled annual exams for participants in the intervention group and for participants in the control group. Therefore, scheduling procedures in the retention study were integrated with existing scheduling procedures in the PLCO Trial.

Retention Study Intervention:

In addition to scheduling annual screening appointments for the intervention group and control group retention study participants, Ms. Randolph proactively calls the DOD-I participants once a month. During each call, she ascertains participants' human services/ information needs (e.g., health insurance information, physician referral, health care condition-specific information, and local physicians who will see uninsured patients). Ms. Randolph leaves voice mail messages including her office telephone number for the DOD-I participants with whom she is unable to speak personally after repeated attempts to speak with them. When Ms. Randolph leaves these messages, she reiterates the fact that she is serving as a resource person for the participant.

Task 1 (d): *Conduct preliminary statistical analyses of the retention intervention (months 8-28)*

Group comparisons between two categorical variables such as group and education were conducted using likelihood ratio chi-square tests. Group comparisons of mean age were tested using the Student's t-test. No statistically significant differences between the intervention group and the control group were found in terms of education or age (Table 1 and Table 2).

Table 3 shows the correspondence between the month of the year and each type of call made. Introductory calls were made in July 1999, first month follow-up calls were made in August 1999, second month follow-up calls were made in September 1999, etc.

Data shown in Tables 4 and 5 reflect calls made by the Retention Coordinator, Ms. Vernetta Randolph, between July 1, 1999 and January 3, 2000. Table 4 shows that a total of 2,201 calls were made to the participants in the study in which Ms. Vernetta Randolph, spoke with the participant directly, his spouse, or left a message with an answering machine, another family member or an unknown person. For example, during the introductory month, 348 calls were made to the 301 participants in the intervention arm of the study. Direct contact with a participant was made for 148 or 42% of these calls. It is important to note that this number (148) may reflect multiple contacts with each participant during that month.

The scripts used when an answering machine is encountered or when the participant is not available are included in Appendix C. In each case, whenever a message is left, Ms. Randolph states her name, the name of the PLCO Cancer Screening Trial, and indicates that she is the participant's resource person. She also provides her telephone number at work and lets the participant know that he can call her at anytime if he or a family member, friend or neighbor would like information on any topic related to health or human services. Thus, whether a participant is contacted directly or receives a message from Ms. Randolph, the concept of having Ms. Randolph as a resource person is reinforced. Additionally, Ms. Randolph repeatedly attempts to speak directly with each participant each month, even if she has previously left a message for the participant during the same month.

Table 5 shows the number of calls made in which Ms. Randolph was able to speak directly with the study participant. As may be seen, with the exception of the incomplete data for the 6th month follow-up calls (January 2000), approximately half of the participants were spoken with directly each month. The lower number of participants with whom Ms. Randolph spoke directly in December, (the fifth month follow-up calls) was probably due to the fact that the participants were more difficult to reach during the holiday season.

Table 1

Educational Characteristics of Intervention Group Members vs. Control Group Members

	Intervention Group (n=299)	Control Group (n=300)	p-value*
	n (%)	n (%)	
Education			
<8 years	17 (5.7)	14 (4.7)	0.65
8-11 years	56 (18.7)	63 (21.7)	
12 years or completed high school	67 (22.4)	63 (21.0)	
Post high school training other than college	24 (8.0)	35 (11.7)	
Some college	79 (26.4)	71 (23.7)	
College graduate	22 (7.4)	23 (8.0)	
Postgraduate	34 (11.4)	28 (9.3)	

*Based on a chi-square test

Table 2

Age Characteristics of Intervention Group Members vs. Control Group Members

	Intervention Group (n=301)	Control Group (n=300)	p-value
	n (s.d.)	n (s.d.)	
Mean Age (s.d.)	66.48 (6.3)	66.6 (6.0)	0.84

Table 3

Correspondence Between Month of the Year and Each Type of Call Made

Month of the Year	Type of Call Made
July 1999	Introductory Call
August 1999	1 st Month Follow-up Call
September 1999	2 nd Month Follow-up Call
October 1999	3 rd Month Follow-up Call
November 1999	4 th Month Follow-up Call
December 1999	5 th Month Follow-up Call
January 2000	6 th Month Follow-up Call

Table 4

Disposition of All Calls Made to the 301 Intervention Group Participants
July 1, 1999 - January 3, 2000

	Answering Machine	Unknown Person	Spouse	DOD Participant	Other Family Member	Total
	n (row %)	n (row %)	n (row %)	n (row %)	n (row %)	n (row %)
Intro. Call	115 (33.0)	65 (18.7)	17 (4.9)	148 (42.5)	3 (0.9)	348 (100)
1 st Month Follow-up Call	153 (33.6)	92 (20.2)	23 (5.1)	182 (40.0)	5 (1.1)	455 (100)
2 nd Month Follow-up Call	111 (29.1)	75 (19.7)	25 (6.6)	168 (44.1)	2 (0.5)	381 (100)
3 rd Month Follow-up Call	106 (30.5)	59 (17.0)	23 (6.6)	157 (45.2)	2 (0.7)	347 (100)
4 th Month Follow-up Call	103 (30.9)	44 (13.2)	20 (6.1)	163 (48.9)	3 (0.9)	333 (100)
5 th Month Follow-up Call	87 (33.5)	35 (13.5)	10 (3.8)	127 (48.8)	1 (0.4)	260 (100)
6 th Month Follow-up Call	20 (25.9)	15 (19.5)	6 (7.8)	35 (45.5)	1 (1.3)	77 (100)
Total Calls	695 (31.6)	385 (17.5)	124 (5.6)	980 (44.5)	17 (0.8)	2201 (100)

Table 5

Number of Participants Reached Directly During Most of the First Six Months of the Study
(July 1, 1999 - January 3, 2000) in Which the Retention Coordinator Was Able to
Speak Directly with the Study Participant

	Calls Made	
	n*	(%)
Introductory Call	144	(47.8)
1 st Month Follow-up	179	(59.5)
2 nd Month Follow-up	166	(55.1)
3 rd Month Follow-up	154	(51.1)
4 th Month Follow-up	156	(51.8)
5 th Month Follow-up	125	(41.5)
6 th Month Follow-up	35	(11.6)

*Based on total sample size of 301 intervention group participants

Task 1 (e): *Conduct final analyses. This task will be conducted during months 28-30.*

Tasks 2 (a & b): (a) *Conduct a literature search of existing instruments assessing cancer screening knowledge, attitudes, and beliefs among African American men (months 1-7) and (b) Use the results of the literature search to document the reliability/validity, purpose and conceptual approach of each measurement instrument, and its cultural appropriateness for African American men (months 1-7)*

Three steps were involved in making progress toward developing a culturally appropriate measurement instrument to assess perceptions of cancer screening among African American men. First, a literature search on this topic was conducted. Potential instrument items that were apparent from this literature search are shown in the following section. The second step involved placing the identified items into a theoretical framework. In this step, the items were grouped into the explanatory framework of the Preventive Health Model.¹ This model, which incorporates concepts from the Health Belief Model,² the Theory of Reasoned Action,³ and the Social Cognitive Theory.⁴ In the third step, a smaller subset of actual focus group items were derived from the list of potential focus group items identified through the literature search.

Step One: Conducting a Literature Search to Identify Potential Survey Items

Focus group items that resulted from this literature search are listed in the following paragraphs of the report. The source of each set of items is identified.

SOURCE: Attitudes of African Americans Regarding Screening for Prostate Cancer. (Robinson and Haynes 1996)⁵

ITEMS:

What do you think would help to motivate Black men to get screened for ____ cancer?
What do you think are the most important reasons many African American men choose not to get screened for ____ cancer?
To what extent do you think that fear and mistrust of the medical establishment will keep Black men from getting screened for ____ cancer?
Do you think that some men fear the exam or test for ____ cancer because it is associated with homosexuality?

SOURCE: Evaluating Focus Group Data: Barriers to Screening for Prostate Cancer Patients. (Dale 1998)⁶

ITEMS:

Does the fact that your doctor is a male/female affect your decision to get prostate cancer screening?
Would embarrassment keep you from getting screened for prostate cancer?
What kinds of things - good or bad - have you heard about the tests for prostate cancer?
Would these things keep you from getting tested for prostate cancer?

SOURCE: Knowledge, Beliefs, and Prior Screening Behavior Among Blacks and Whites Reporting For Prostate Cancer Screening. (Demark-Whahnefried, Strigo, Catoe, Conway, Brunetti, Rimer, and Robertson 1995)⁷

ITEMS:

Do you know someone who has had ____ cancer?
Is it possible to have ____ cancer without having symptoms of this disease?
What motivated you to get checked for ____ cancer?

SOURCE: The Role of Focus Groups in Health Education for Cervical Cancer among Minority Women. (Dignan, Michielutte, Sharp, Bahnson, Young, and Beal 1990)⁸

ITEMS:

Do you think that some people choose not to get screened for ____ cancer because they cannot afford treatment if ____ cancer were found?
Do you have difficulty now in getting regular health care? What are some of the problems you are facing? (Ex: waiting time to get an appointment; waiting time at doctor's office)

SOURCE: Breast Cancer Screening: Racial/Ethnic Differences in Behaviors and Beliefs. (Friendman, Webb, Weinberg, Lane, Cooper, and Woodruff 1995)⁹

ITEMS:

What do you think is your risk of developing ____ cancer, compared to other men of your age?
Do you think that being older or being African American affects your chances of getting ____ cancer?
Does fear keep you from getting screened for ____ cancer?
What are some of your fears related to ____ cancer screening?

Do you think that people don't get _____ cancer screening because they just never get around to it?

Do you think that some people avoid getting screened for _____ cancer because they are afraid to think about cancer?

Do you agree that there is little hope for people with _____ cancer?

Do you think _____ cancer can be cured if it is found early enough?

SOURCE: Cancer Screening among African American Women: Their Use of Tests and Social Support. (Kang, Bloom, and Romano 1994)¹⁰

ITEMS:

Do you think that:

Being married

Being a church member

Being a member of other types of organizations

Being encouraged by relatives and friends

would influence your decision to get _____ cancer screening?

What could your spouse, church, other organization, relative or friend do to encourage your use of _____ cancer screening tests?

**Black-White Differences in Cancer Prevention Knowledge and Behavior.
(Jepson, Kessler, Portnoy, and Gibbs 1991)¹¹**

ITEMS:

Do you think that changing your diet can play a role in whether or not you get cancer?

Have you ever had a stool blood test?

Are you currently a cigarette smoker?

Do you exercise at least three times each week?

SOURCE: Factors Contributing to Health Promotion Behaviors among African-American Men. (Million-Underwood, Sanders 1990)¹²

ITEMS:

Do you think that testing for _____ cancer should be included as a part of your physical exam?

Do you think that doctors and other health care providers should talk to Black men about their cancer risk?

Are you aware of the screening guidelines for _____ cancer?

**SOURCE: Behavioral Interventions to Increase Adherence in Colorectal Cancer Screening.
(Myers, Ross, Wolf, Balshem, Jepson, and Millner 1991)¹³**

ITEMS:

If your doctor verbally recommended that you receive colorectal cancer screening, would this influence you to get the screening?

If you received a letter in the mail from your doctor, suggesting that you get colorectal cancer screening, would this influence you to get the screening?

Which would have the greatest impact on your decision to get screened for colorectal cancer-doctor recommendation (verbal), doctor recommendation (written), community leader recommendation-video or family member/friend recommendation?

Can you describe the kinds of tests that are done to check for colon – rectal cancer? (Ex: FOBT; Flex-sig)

What do you think are the benefits of colorectal cancer screening?

What are some of the drawbacks of this type of screening?

Would you get screened for colorectal cancer even if you hadn't been experiencing any symptoms of this disease?

What are some of the early warning sign of colorectal cancer?

What would be some of the barriers that would keep you from getting barrier that would keep you from getting screened for colorectal cancer? (Ex: cost, discomfort, time, not necessary)

SOURCE: Factors Associated with Intention to Undergo Annual Prostate Cancer Screening among African American Men in Philadelphia. (Myers ,Wolf, McKee, McGrory, Burgh, Nelson, and Nelson 1996)¹⁴

ITEMS:

Belief in the salience and coherence of screening

Belief in the efficacy of screening

Belief in the residual value of screening

Concern about screening-related physical discomfort and embarrassment

Screening-related influence of family members and friends

Do you think that the quality of your life would be better if you were tested for prostate cancer than if you were not tested?

Do you know what some of the possible health outcomes of prostate cancer treatment are?

Probe for: Incontinence

Impotence

Urethral Structure

Rectal Injury

Gynecomastion

SOURCE: Perceptions of Colorectal Cancer In a Socioeconomically Disadvantaged Population. (Price 1993)¹⁵

ITEMS:

Do you think homosexual men are more likely than other men to get colorectal cancer?

Do you think exercising regularly will affect your chances of getting colon cancer?

What about eating foods high in fat – does this affect risk of getting colon/rectal cancer?

Do you think that colon/rectal cancer runs in families? If so, what does this imply about cancer screening for members of these families?

Do you think poor, older, or Black people are more likely than other people to get colon cancer?

Does having hemorrhoids increase risk of getting colon/rectal cancer?

Do you think that people who have regular check-ups by their doctor need to worry about getting _____ cancer?

Which exams are used to detect colon/rectal cancer?

Are you embarrassed by the exams to detect colon/rectal cancer?

What would be some things that would keep you from getting checked for ____ cancer even if you wanted to get checked?

SOURCE: Prostate Cancer: Perceptions of African-American Males. (Price, Colvin, and Smith 1993)¹⁶

ITEMS:

What are some of the early warning signs of prostate cancer?

Can prostate cancer be prevented?

Have you ever talked to your doctor about having your prostate examined?

Do you think that African American men are at higher risk than other men of developing prostate cancer?

Does age have anything to do with likelihood of getting prostate cancer?

Are straight or gay men more likely to develop prostate cancer?

Compared to other men your age, do you think you are more or less likely to develop prostate cancer?

What are some of the benefits of prostate cancer screening?

What do you think are some of the barriers to prostate cancer screening among Black men? (Probe for fear, shame, cost, time, uncomfortable exam, etc.)

SOURCE: African-American Males and Prostate Cancer: Assessing Knowledge Levels in the Community. (Smith, DeHaven, Grundig, and Wilson 1997)¹⁷

ITEMS:

What is ____ cancer?

Do you think people with ____ cancer can live a normal life if they are treated for this disease?

SOURCE: Knowledge, Beliefs, Attitudes, and Cancer Screening Among Inner-City African-American Women. (Sung, Blumenthal, Coates, and Alema-Mensah 1997)¹⁸

ITEM: Are there people in your life with whom you discuss cancer?

SOURCE: Using Focus Group Methodology to Develop Breast Cancer Screening Programs That Recruit African American Women. (Williams, Abbott, and Taylor 1997)¹⁹

ITEMS:

Do you think that health care facilities are open at convenient times to allow ____ cancer screening?
Perception and Efficacy:

Do you think that the results of ____ cancer screening are reliable?

Do you think that most people would have transportation to a health care facility if they decided to get screened for ____ cancer?

What are some ways you could learn more about ____ cancer?

(Probe: Brochures, flyers and pamphlets from doctors' offices and in communities; radio ads; billboards; newspapers; church bulletins; and magazine ads)

Do you think that ____ screening advertising that featured well known African American men to get screened for ____ cancer?

What do you think messages designed to encourage Black men to get screened for ____ cancer should say?

What do you think would be the best format for these messages? (Probe for print ads, TV, radio, magazines, etc.)

What role does spirituality play in the decision to get screened for ____ cancer?

Task 2 (c): *Use the results of the literature search to develop focus group questions (months 8-12)*
Step Two: Placing the Identified Potential Survey Items Into a Theoretical Framework

In the Preventive Health Model, four sets of factors are posited to be related to preventive intention and to carrying out this intention by actually engaging in preventive behavior.²⁰ These factors are background factors, cognitive/psychological representation factors, social support and influence factors, and program factors. Background factors include sociodemographic characteristics, medical history, and past preventive behavior. Cognitive/psychological representation factors include perceived susceptibility to disease, worry about having the disease, interest in knowing diagnostic status, belief in disease prevention and curability, belief in salience and coherence of behavior, belief in efficacy of detection and treatment, belief in self-efficacy related to behavior, and concern about behavior-related discomfort. The social support and influence factor encompasses the support and influence of family members and health care professionals. Finally, program factors include provider actions that facilitate (or inhibit) preventive behavior.²⁰

The classification scheme of the Preventive Health Model, used to categorize each potential survey item identified through the literature search, is presented in the following section of the report.

Potential Survey Items that Are Background Factors:

Which of these groups best describe(s) you? (African American or Black, American Indian or Alaskan Native, Asian, Caucasian or White, Pacific Islander, or Other ____ (Specify))

Is there another group with which you identify? If so, with which group? (African American or Black, American Indian or Alaskan Native, Asian, Caucasian or White, Pacific Islander, or Other ____ (Specify))

Are you of Hispanic origin? (Yes or No)

What is your date of birth?

Are you male or female?

Are you currently a cigarette smoker?

Do you exercise at least three times each week?

What is the highest grade or level of schooling you completed?

What is your current marital status?

Which of these categories best describes your current working situation? (Homemaker, Working, Unemployed, Retired, Extended Sick Leave, Disabled, Other ____ (Specify))

(Medical history will be obtained from the survey participants' medical records)

(Income will be obtained through the process of geocoding)

Potential Survey Items that Are Cognitive/Psychological Representation Factors:

Perceived susceptibility to disease - Is it possible to have cancer without having symptoms of this disease?

Are you aware of the screening guidelines for cancer?

Can you describe the kinds of tests that are done to check for cancer?

Would you get screened for cancer even if you had not been experiencing any symptoms of cancer?

What are some of the early warning signs of cancer?

What is cancer?

Do you know someone who had had cancer?

Do you think that poor people are more likely than other people to get cancer?

What do you think is your risk of developing cancer, compared to that of other men your age?

Do you think that being older affects your chances of getting cancer?

Do you think that cancer runs in families? If so, what does this imply about cancer screening for members of these families?

Do you think that African American people are more likely than other people to get cancer?

Worry about having the disease - What are some of your fears related to cancer screening?

Do you know what some of the possible side effects of cancer treatment are?

Interest in knowing diagnostic status - Do you think that some people avoid getting screened for cancer because they are afraid to think about cancer?

Belief in disease prevention and curability - What do you think are the most important reasons many African Americans choose not to get screened for cancer?

Do you think that the quality of your life would be better if you were tested for prostate cancer than it would be if you were not tested?

Do you think that people who have regular check-ups by their doctor need to worry about getting cancer?

Belief in salience and coherence of behavior - Do you think that some people do not get cancer screening because they just never get around to it?

Belief in efficacy of detection and treatment - Do you think that the results of cancer screening tests are accurate?

Do you think cancer can be cured if it is found early enough? If so, do you think that once they are cured, people can live a normal life?

What do you think are the benefits of cancer screening? Would these things motivate you to get tested for cancer?

What are some of the drawbacks of cancer screening? Would these things keep you from getting tested for cancer?

Belief in self-efficacy related to behavior - What would be some things that would keep you from getting checked for cancer even if you wanted to get checked?

Do you think that most people would have transportation to a health care facility if they decided to get screened for cancer?

Do you think exercising regularly will affect your chances of getting cancer?

What about eating foods high in fat - does this affect your chances of getting cancer?

Concern about behavior-related discomfort - Do you think that some men associate certain tests for cancer with being a homosexual (a man who prefers dating men)?

Would embarrassment keep you from getting screened for cancer?

Potential Survey Items that Are Social Support and Influence Factors:

Do you think that:

- Being married
- Being a church member
- Being a neighbor
- Being a member of other types of organizations
- Being encouraged by relatives and friends

would influence your decision to get cancer screening? In what ways?

Which types of people or organizations would have the greatest influence over your decision to get screened for cancer?

Are there people in your life with whom you discuss cancer?

What do you think would help to motivate African American men to get screened for cancer?

What are some ways you could learn more about cancer?

- Brochures/pamphlets
- Flyers
- Radio ads

Television ads
Newspaper ads
Church bulletins
Magazine ads
Billboards

Potential Survey Items that Are Program Factors:

To what extent do you think that fear and mistrust of the medical establishment keep Black men from getting screened for cancer?

Does the fact that your doctor is a male/female affect your decision to get cancer screening?

Do you think that some people choose not to get screened because they cannot afford treatment if cancer were found?

Has your doctor ever talked to you about having a cancer screening test?

If you have ever had a cancer screening test, did you talk to your doctor before you had the screening test? Did you talk to your doctor after you had the screening test?

What do you think messages designed to encourage African American men to get screened for cancer should say?

Do you have difficulty now in getting regular health care? If so, what are some of the problems you are facing?

Do you think that doctors and other health care providers should talk to African American men about their cancer risk? If so, what do you think these providers should say?

Do you think that testing for cancer should be included as a part of your regular physical exam?

Do you think that health care facilities are open at convenient times to allow cancer screenings?

Step Three: Developing a smaller subset of actual focus group items derived from the list of potential items identified through the literature search.

The focus group moderator's guide, including the final list of focus group items, is presented in the following section of the report.

**Focus Group Questions for Cancer
Screening Survey Development**

Facilitator: Marvella Ford

Assistant: Deanna Hill

Recorder: Felecia Collins

Tuesday, January 25, 2000

6:00 p.m. - 8:00 p.m.

I. WARM-UP AND EXPLANATION (10 minutes)

A. Introduction

1. Good evening. My name is Marvella Ford. I work here at Henry Ford Health System. This is Deanna Hill. Deanna also works here at Henry Ford Health System. She will be assisting us this evening. Felecia Collins is the recorder this evening.
2. Thanks for coming.
3. Your presence and participation are important. Your thoughts and opinions that you discuss tonight are valuable in helping us to develop a survey about cancer screening.

B. Purpose

1. What we are doing here this evening is called a focus group. It's a discussion to find out your opinions.
2. We are interested in all of your ideas, comments and suggestions.
3. Each of you is very important and all of your comments are welcome.
4. There are no right or wrong answers.

Please speak up -- even if you disagree with someone else here. It's important that we hear what each of you thinks.

C. Procedure

1. We will be audiotaping and videotaping our discussion. Everything you say is important to us, and we want to make sure we don't miss any comments. Later we'll go through all of your comments and use them to prepare a report on our discussion. However, all of your comments are confidential and will be used only for research purposes. Nothing you say will be connected to your name. Also, if any questions make you uncomfortable, feel free not to

answer them.

2. You don't have to wait for me to call on you. However, please speak one at a time, so the tape recorder can pick up everything.
3. We have many topics to discuss so I may change the subject or move ahead. Please stop me if you want to add anything.

D. Self-Introductions (Ice Breaker)

1. Please tell us your name and your dream vacation.

FOCUS GROUP QUESTIONS

1. What things come to mind when you hear the word "cancer"?

How do you feel when these things come to mind?

I typically use the words "African American" or "Black" but I was wondering which one you prefer to use? (USE THE WORD THEY PREFER. IF THEY DO NOT HAVE A PREFERENCE, USE "AFRICAN AMERICAN" AND "BLACK" INTERCHANGEABLY.)

2. What do you think are some of the reasons some African American men choose not to get screened for cancer? Cancer screening means getting checked for cancer before you've ever had it.
3. Which types of people or organizations do you think have the greatest influence over the decision of Black men to get screened (or checked) for cancer?

Probe: spouse, neighbor, relatives, friends, church members, pastor, etc.

4. How much of a role do you think religion or spirituality play in the decision of Black men to get screened (or checked) for cancer?
5. What do you think are some of the benefits of cancer screening (or getting checked for cancer before you've ever had it)?

Do you think that these benefits motivate some Black men to get screened (or checked) for cancer?

6. What do you think are some of the drawbacks of cancer screening?

Do you think that these drawbacks keep some Black men from getting screened (or checked) for cancer?

7. What things do you think would motivate Black men to get screened (or checked) for cancer?
8. To what extent do you think that fear and mistrust of the medical system keep Black men from getting screened (or checked) for cancer?
9. Would the cost of cancer treatment if cancer is found keep you from getting screened (or checked) for cancer?
10. How much would embarrassment keep you from getting screened (or checked) for cancer?
11. What are some of your fears about cancer screening?
12. Do you think that people who have regular check-ups by their doctor need to worry about getting cancer?

What makes you say this?

13. Do you have difficulty now in getting regular health care?

If so, what are some of the problems you are facing (Probe: waiting time to get an appointment; transportation problems; cost; time away from work)

14. Do you think that testing for cancer should be included as part of the physical exam done by your doctor?

What makes you feel this way?

15. Do you think that doctors and other health care providers should talk to Black men about their cancer risk?

(If yes, probe: What kinds of things do you think doctors and other health care providers should say to Black men about their cancer risk?)

16. Does your doctor talk to you about your risk of getting cancer?

(If yes, probe: What kinds of things does your doctor talk to you about, in terms of your risk of getting cancer?)

17. What could your doctor do to encourage you to get screened (or checked) for cancer?

(Probe: verbal recommendations and/or letters suggesting screening)

18. Do you think that health care clinics and hospitals are open at convenient times for cancer screening (or getting checked for cancer before you've ever had it)?

(If not, probe: What could be done to make the times more convenient for people to get cancer screening?)

19. Do you think that using t.v., radio, newspaper and magazine ads to encourage Black men to get screened (or checked) for cancer would be effective?

(Probe for reasons why or why not: Let's start with t.v. ads...Now, let's talk about radio ads.)

(Probe: If men think ads would be effective say: What should these ads look or sound like? Who should be in them?)

20. How accurate do you think that the results of cancer screening tests are?
21. How likely do you think it would be for you to have cancer without having any signs or symptoms?
22. Do you know someone who has had cancer?
23. Do you think cancer can be cured if it is found early enough?

What makes you feel this way?

24. Do you think that people who have had cancer can live a normal life?

What makes you feel this way?

25. Do you think that your life would be better if you were screened (or checked) for cancer than it would be if you were not screened (or checked) for cancer?

(Probe: In what ways would your life be better? In what ways would your life not be better?)

26. Do you think that some men associate certain cancer screening tests with homosexuality or with men who prefer to date other men)?
27. How do you think that being older affects your chances of getting cancer?
28. How do you think that being African American affects your chances of getting cancer?
29. What do you think your risk is of getting cancer, compared to other men your age?

Thank you very much for coming today. Your comments are greatly appreciated. Everything that you have said tonight will help us to prepare a survey to look at perceptions of cancer screening.

Again, thank you very much.

Task 2 (d): Hold a focus group session to assess participants' perceptions of the developing measurement instrument and to garner ideas for new questions (month 13)

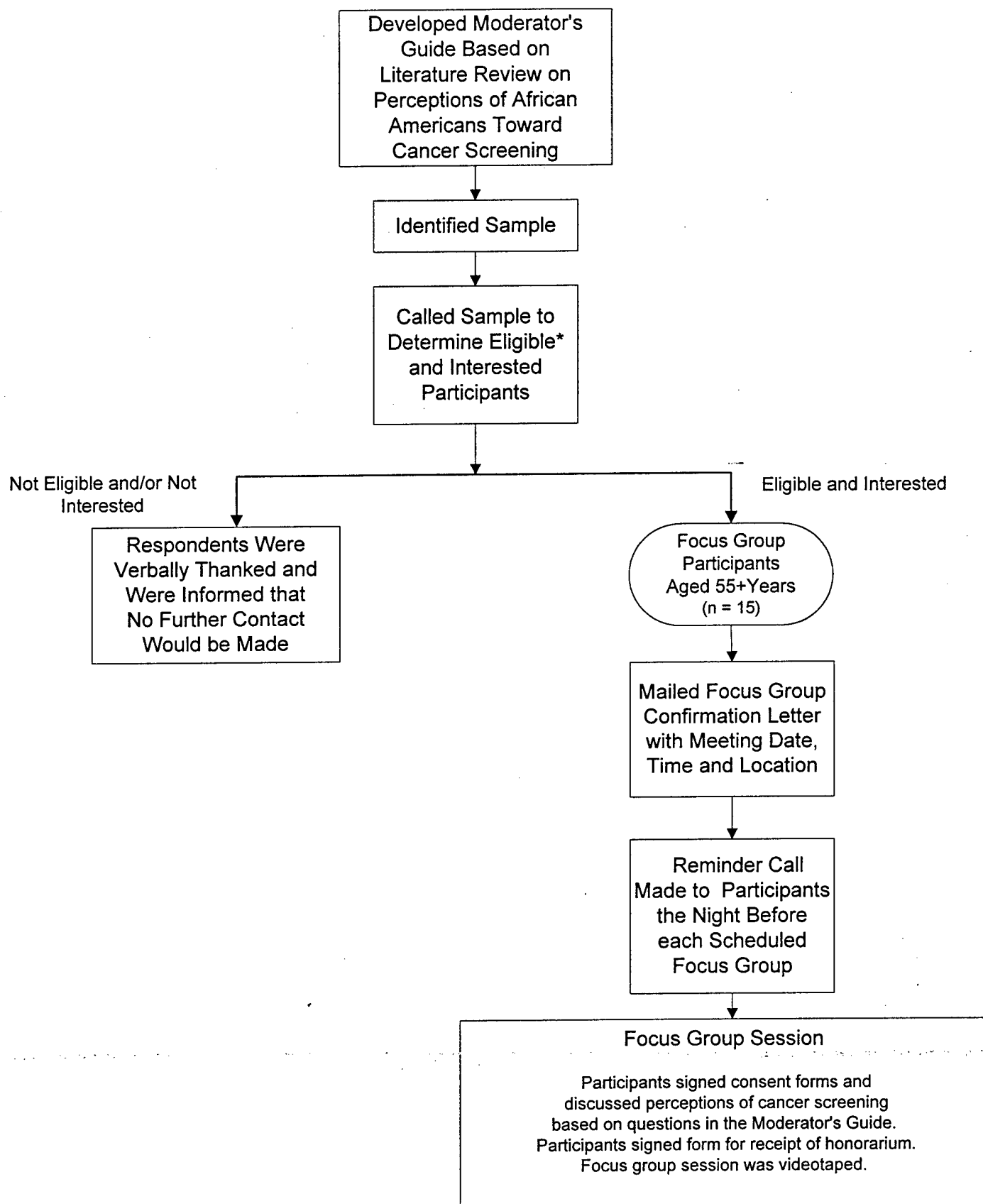
The study processes involved in identifying focus group participants are depicted in Figure 2. Basically, all African American men who had made at least one visit to Henry Ford Health System in the past year, and who were over the age of 55 years, were selected. Then, the names and birthdates of the men on this listing were compared with the names and birthdates of the African

American men in the PLCO Trial. Men who were part of the PLCO Trial were excluded from participating in the focus group.

A random sample of the remaining names was taken, and given to trained telephone interviewers, who called the men on the list to invite them to participate in the focus group. During the telephone call, the interviewers confirmed the age and race of the men, and confirmed that they were not taking part in the PLCO Trial. If the men were not interested or able to participate in the focus group, they were verbally thanked for their time in taking the invitational telephone call. If the men were interested and able to come to the focus group, they were thanked. The interviewer continued calling the men until 15 men indicated that they would like to participate in the focus group. These men were then sent a reminder letter confirming the date, time, and location of the focus group. The night before the focus group was scheduled to take place, the 15 men received a reminder telephone call. At the conclusion of the focus group, the men signed a receipt and received \$25 in cash as an honorarium. Ten men participated in the focus group. These men ranged in age from 55-87, with a mean age of 73.4. The age of the men was fairly evenly distributed by decade.

Figure 2

Methods Used in the Focus Group



*confirmed age, race/
ethnicity, and gender

Although a transcript of the focus group is not yet available, a sample of the focus group discussion, based on notes taken during the focus group, is included in the following paragraphs. The focus group transcript will be analyzed to ascertain the major constructs of apparent importance to the participants in the focus group. Appendix D contains copies of the telephone scripts, reminder letter, consent form, and receipt used in conducting the focus group.

Question: Do you know someone who has had cancer?

Responses: "Anyone who has had a family member or friend die from cancer will be very reluctant to go get tested for it. If you see people suffer you will be very reluctant to get tested... Black men are more apt to get prostate cancer. I get those tests but nothing else."

"It's on the same side (of my family) as diabetes."

"I worked with a guy who thought he had a peanut caught in his throat and he had cancer. Now I want to get checked every time I feel something is there or not."

Question: Which kinds of cancer screening tests do doctors suggest you have?

Responses: "Each time you have a physical your doctor should go through your records and they should know when your next examination is".

"What good is it to test for cancer? The only evidence is when you have symptoms."

"Every doctor that I have gone to always tests for prostate cancer."

"Women, the drive that every woman should have mammograms, should be done for men."

Question: What are some things that keep you from getting screened for cancer?

Responses: "It's uncomfortable."

"Yeah, it's uncomfortable".

"I never associated the prostate with being checked for cancer."

"I don't know if I've ever had a PSA test or not."

Question: What are the benefits of getting screened for cancer?

Responses: "Longer life, the pleasure of just being able to urinate."

"Relief."

"Quality of life is better."

Question: If your doctors suggested that you get screened for cancer, would you follow up on this suggestion?

Responses: "Of course."

"I have avoided tests and x-rays. There is a difference between retired guys and guys who work. Retired guys can go to the doctor more often."

"I will take a test whether there is a reason to or not. I trust my doctor enough (to take a test) if asked to take a test."

"It's not a question of trust, it's a question of priorities."

"If your car goes bad you will put it in the shop. But with your body, you wait (to seek health care)."

"I have no qualms with doctors making sure I have all my tests. They keep me updated on all my tests."

Question: What would help you to get screened for cancer?

Responses: "Groups like this."

"Family awareness."

"I wish I would get reminder letters."

"It would help if the medical records were computerized... I'm talking about a special department. They should have profiles of people so that if someone comes in with symptoms one time, and other symptoms another time, the computer will scan the record and make a health profile for the person. Then, the computer can send a letter to the person saying, 'It looks as if you may be at risk for (x) disease'."

"If you don't get a notice you just forget about it."

"The most effective way is advertisements."

"The t.v."

Question: Would reading a pamphlet help to motivate you to get screened for cancer?

Responses: "People throw away pamphlets."

Task 2 (e) – (i): *(e) Based on the focus group results, revise the measurement instrument. (f) Hold a focus group session to assess participants' perceptions of the revised measurement instrument. (g) Incorporate participants' suggestions into a further refinement of the instrument. (h) Conduct statistical analyses of the pilot study results. (i) Revise and refine the final measurement instrument, based on the pilot study results.*

These tasks will be conducted during months 14-30.

KEY RESEARCH ACCOMPLISHMENTS

- An abstract documenting the design of the funded research was submitted for presentation at an upcoming AACR conference.
- Because of the nature of this study, Dr. Ford was invited to participate in the National Cancer Institute, Division of Cancer Control and Population Sciences Workshop on Behavioral Intervention Research and Assessment for Colorectal Cancer Screening. This meeting took place December 9-10, 1999 in Washington, D.C. The purpose of the meeting was to assess the status of behavioral research related to colorectal cancer screening.
- Dr. Ford was invited to participate in the National Cancer Institute's Colorectal Cancer Progress Review Group Roundtable. The goal of the Roundtable, which took place January 5-7, 2000, was to establish a national research agenda for colorectal cancer.
- A focus group assessing the perceptions of older African American men toward cancer screening was conducted.
- A questionnaire is being developed that will assess perceptions of African American men toward cancer screening. The concepts in this questionnaire are being modeled after the concepts in the Preventive Health Model.¹ In a future study, the factor structure of the newly developed questionnaire could be compared with the theoretical framework found in the Preventive Health Model.¹

REPORTABLE OUTCOMES

Manuscripts, abstracts, presentations: An abstract describing the retention study was submitted on November 1, 1999 for consideration as a presentation at the American Association of Cancer Research Conference in April 2000. The abstract is described in the following paragraphs.

Retaining African American Men in a Cancer Screening Trial: Challenges, Solutions, and Focus Group Results. Ford ME, Swanson GM, Vernon S, Hill D, Jankowski M, Randolph V, Johnson CC. *Resource Center for Minority Aging Research and Josephine Ford Cancer Center, Henry Ford Health System, Detroit, MI 48202*

This presentation describes challenges faced in carrying out a retention study involving African American men and solutions to these challenges. The objective of the retention study, begun in July 1999, is to identify innovative methods for increasing the retention of African American men in prostate cancer screening trials. Retention, while important for all groups, is especially critical for African American men, given their often low representation in clinical trials. The specific aims are to evaluate the efficacy of an intervention designed to retain African American men in the screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial at the Henry Ford Health System site, and to develop a culturally appropriate measurement instrument to assess perceptions of screening for these cancers among older African American men. The study population consists of African American men aged 55 and older living in the Detroit area. Blocked randomization methods were used to assign the men to the retention intervention or control group. A retention coordinator provides intense follow-up to the men in the intervention group and guides them through the PLCO Trial cancer screening processes. It is hypothesized that men in the intervention group will show higher screening adherence rates than men in the control group. An instrument to assess cancer screening perceptions among older African American men will be

developed using focus group techniques. The results of these focus groups are described in the presentation.

CONCLUSIONS

Issues related to the implementation of the behavioral intervention and other aspects of the study protocol

The behavioral intervention has been designed to overcome barriers to continued trial participation. The main element of the intervention is a retention coordinator, who establishes and maintains monthly telephone-based contact with PLCO Trial participants in the intervention arm of the study, and who serves as a source of information about relevant health and social services. This intervention is based upon the systems approach in the field of social work, in which a case manager serves as a link between clients and needed resources and resource systems by serving as a source of information about these resources and systems. While somewhat more limited in breadth than a traditional case manager, the retention coordinator nonetheless attempts to maintain a similar depth of personal relationships with the PLCO Trial participants as a case manager would with her or his clients.

Four barriers to the participation of minority populations in clinical trials have been identified by Swanson and Ward.²¹ These are sociocultural barriers, economic barriers, individual barriers, and barriers inherent in study design, which can affect not only recruitment to cancer screening trials but also continued participation in these trials as well. The innovative telephone-based retention strategy administered by a retention coordinator has been designed to address these barriers to continued trial participation. *Sociocultural Barriers* - These barriers include fear and mistrust of federally sponsored projects. In the present study, the retention coordinator, a person of the same race as the study participants, aims to develop rapport with the participants and build a sense of trust with them. The retention coordinator provides participants and their spouses/partners with requested information pertaining to the PLCO Trial as well as other questions they have related to health and social services. *Economic Barriers* - These barriers are addressed in the proposed recruitment study. The retention coordinator serves as a clearinghouse for information related to older adults and their families, such as that provided by local Area Agencies on Aging and local senior centers. Addressing issues of importance to participants may help to free them from some economic worries, thus allowing them to focus on their cancer trial participation. *Individual Barriers* - Individual barriers include denial and underestimation of personal vulnerability. It is hoped that the customized approach of the telephone calls from the retention coordinator will reduce individual barriers to participation as well as sociocultural barriers, as health issues pertinent to older African American men are addressed during these telephone conversations. *Barriers Inherent in Study Design* - The proposed study is designed to minimize barriers inherent in study design, which Swanson and Ward²¹ point out can significantly reduce study participation rates. The retention coordinator guides the men assigned to the intervention arm of the study through the PLCO Trial screening processes.

Challenges and Solutions

- (a) Originally, the retention coordinator was only going to contact men assigned to the intervention arm of the present study. Existing PLCO Trial schedulers would make screening appointments for men assigned to the control arm of the study. However, one of the co-investigators pointed

out the fact that this could serve to introduce bias into the study. The study protocol has been changed so that the retention coordinator now makes all of the contacts with the all of the men in the study. This protocol change will help to reduce bias that might be associated with style differences in interacting with the study participants. The retention coordinator contacts the men in the intervention arm (n=301) by telephone on a monthly basis and also schedules yearly PLCO Trial cancer screening appointments for the men in the control arm (n=300) of the study.

- (b) During the first two months of the study, the retention coordinator was not able to speak via telephone with 35 men because they were not available when she called. After some discussion, the research team made the decision that the retention coordinator would leave messages on the answering services of the men. In the message, the retention coordinator introduces herself as a resource person for the men, and lets them know that she is will call them on a monthly basis, and that she is available to help them to find answers to questions they or their family may have. At the end of the message, the retention coordinator leaves her telephone number, and asks the participant to call her. The retention coordinator now leaves similar messages with all men she is not able to speak with directly when making the monthly calls, although she continues to call them throughout each month in an attempt to speak directly with them.
- (c) In order to maximize the number of intervention group participants with whom the Retention Coordinator speaks directly each month, the process of mailing requested information has been delegated to a staff secretary. We did not expect study participants to ask for as great an amount of information as they are currently requesting. Information is being requested related to transportation, food services, recipes, medication, various diseases, literacy, housing, social security, and child care. For example, the retention coordinator has been asked by the spouses of study participants for information related to the participant's grandchildren. Because of the volume of information requested, the responsibility of mailing information to participants has been given to a staff secretary. The secretary now generates the cover letters accompanying the mailed materials. The Retention Coordinator then signs the cover letters, and the completed information packets are then mailed by the secretary. During the planning stage of the study, the retention coordinator contacted a number of local agencies to receive information related to the services provided by these agencies. A file was developed listing the agencies and the services provided. This file serves as a source for locating information requested by study participants. Other sources of information include the Internet, the Yellow Pages, radio and television announcements, agency newsletters, and a directory of local human services. A listing of community resources used in the study is included in Appendix D.
- (d) In a previous study involving recruitment of African American men to the PLCO Cancer Screening Trial, it was discovered that the men's female spouses/partners served as gatekeepers. If the women did not think their spouses/partners should participate in the PLCO Trial, the women would not give the telephone to them during the recruitment calls. Therefore, in the retention study, the intervention was designed to include female spouses/partners in order to garner their support for the project, and to potentially serve to help retain the men in the study. For example, during each telephone call, the retention coordinator asks to speak with the participant's spouse/partner, if he has one. If the retention coordinator has not spoken previously with the spouse/partner, the retention coordinator then introduces herself and asks if they would like information related to particular topics. If the retention coordinator has spoken previously with the spouse/partner, the retention coordinator follows up on previous conversations, and gives the spouse/partner information they requested.

- (e) The retention coordinator maintains computerized files detailing which men have been contacted each month. During the third month of the study, the retention coordinator noted that it would be helpful not only to know which men were called, and which still needed to be called each month but also the time of day and day of the week when the men were reached. The retention coordinator felt that this additional information would assist her in successive months to contact the men during a time when they could be reached. Subsequently, information related to the time of day and day of the week each participant was reached was added to the computerized files.

In summary, the findings of this study can be used to help African American men benefit from the positive aspects of participation in prostate cancer research. The focus group findings will lay the foundation for a future study designed to assess differences in perceptions of cancer screening among African American men of different ages, and to identify potential drop-outs, who could then receive the intensive follow-up provided by a retention coordinator. The study has gone well during the approximately six months that the retention intervention has been implemented to date. A number of challenges have been encountered and solutions to these challenges have been proposed.

References

1. Vernon SW, Myers RE, Tilley BC. Development and validation of an instrument to measure factors related to colorectal cancer screening adherence. *Cancer Epidemiology, Biomarkers, and Prevention* 1997;6:825-832.
2. Strecher, VJ, Rosenstock, IM. The Health Belief Model. In Glanz K, Lewis FM, Rimer B (ed.), *Health Behavior and Health Education*. San Francisco, C.A.: Jossey Bass Publishers 1997;41-59.
3. Ajzen IFM. *Understanding attitudes and predicting social behavior*. Englewood Cliffs, N.J.: Prentice-Hall, 1980.
4. Bandura A. *Social foundations of thought and action: a social cognitive theory*. Englewood Cliffs, N.J.: Prentice-Hall, 1986.
5. Bradshaw R, Ashley M, Haynes MA. Attitudes of African Americans regarding screening for prostate cancer. *Journal of the National Medical Association* 1996; 88:241-246.
6. Dale W. Evaluating focus group data: barriers to screening for prostate cancer patients. *Analytic Approach* 1987;21:116-128.
7. Denmark-Wahnefried W, Strigo T, Catoe K, Conaway M, Brunetti M, Rimer BK, et al. Knowledge, beliefs, and prior screening behavior among blacks and whites reporting for prostate cancer screening. *Urology* 1995;46:346-351.
8. Dignan M, Michielutte R, Sharp P, Bahnson J, Young L, Beal P. The role of focus groups in health education for cervical cancer among minority women. *Journal of Community Health* 1990;5:369-375.
9. Friedman LC, Webb JA, Weinberg AD, Lane M, Cooper HP, Woodruff A. Breast cancer screening: racial /ethnic differences in behavior and beliefs. *Journal of Cancer Education* 1995;10:213-216.
10. Kang SH, Bloom JR, Romano PS. Cancer screening among African American women: Their use of tests and social support. *American Journal of Public Health* 1994;84:101-103.
11. Jepson C, Kessler LG, Portnoy B, Gibbs T. Black-white differences in cancer prevention knowledge and behavior. *American Journal of Public Health* 1991;81:501-504.
12. Millon-Underwood S, Sanders E. Factors contributing to health promotion behaviors among African-American men. *Oncology Nursing Forum* 1990;17:707-712.
13. Myers R, Ross EA, Wolf TA, Balshem A, Jepson C, Millner L. Behavioral Interventions to Increase Adherence in Colorectal Cancer Screening. *Med Care* 1991; 29:1039-1050.

References (cont'd)

14. Myers RE, Wolf TA, McKee L, McGrory G, Burdh DY, Nelson G et al. Factors associated with intention to undergo annual prostate cancer screening among African American men in Philadelphia. *American Cancer Society* 1996;78:471-479.
15. Price JH. Perceptions of colorectal cancer in a socioeconomically disadvantaged population. *Journal of Community Health Nursing* 1993;18:347-362.
16. Price JH, Colvin TL, Smith D. Prostate cancer: perceptions of African-American males. *Journal of The National Medical Association* 1993;85:941-947.
17. Smith GE, DeHaven MJ, Grundig JP, Wilson GR. African-American males and prostate cancer: assessing knowledge levels in the community. *Journal of the National Medical Association* 1997;89:387-391.
18. Sung JFC, Blumenthal DS, Coated RJ, Alema-Mensah E. Knowledge, beliefs, attitudes. and cancer screening among inner-city African-American women. *Journal of the National Medical Association* 1997;89:405-411.
19. Williams GA, Abbot RR. Using focus group methodology to develop breast cancer screening programs that recruit African American women. *Journal of Community Health* 1997;22:45-56.
20. Myers RE, Chodak GW, Wolf TA, Burgh DY, McGrory GT, Marcus SM, Diehl JA, Williams M. Adherence by African American ment to prostate cancer education and early detection. *Cancer* 1999; 86: 88-104.
21. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. *Journal of the National Cancer Institute* 1995;87:1747-1759.

APPENDIX COVER SHEET

- A. IRB Approval for 1999 and 2000
- B. Consultant Meeting Agenda
- C. Scripts Used in the Retention Intervention
- D. Recruitment Telephone Scripts, Reminder Letter, Consent Form, and Honorarium Receipt Used in the Focus Group
- E. Listing of Community Resources to which the Retention Coordinator Refers Study Participants



HENRY FORD HEALTH SCIENCES CENTER

HUMAN RIGHTS COMMITTEE (IRB)

REQUEST FOR EXPEDITED REVIEW OF AMENDMENT/REVISED CONSENT FORM

Research Administration
CFP-1
2799 West Grand Boulevard
Detroit, MI 48202-2689
(313) 876-2024 Office
(313) 876-2018 Fax

Thomas Roth, PhD
Director of Research

Lynne M. Pecze, MHA
Administrative Director,
Research

S. David Nathanson, MD
Chair, Care of Experimental
Animals Committee

Ira Wollner, MD
Chair, Human Rights Committee

Leonard Lutter, PhD
Chair, Small Projects
Funding Committee

Principal Investigator: Marvella Ford

Signature of Principal Investigator: _____

Project Title: African - American Men in the
PLCO Trial: Developing & Testing Methods...

IRB Ref. # _____ IRB Approval Period 10/14/98 - 10/13/99

RE: _____

1.0 Reason for IRB review (see instructions on back):

- ☒ Protocol Amendment ☐ Advertisement ☐ Investigator Brochure Update
☒ Revised Consent Form ☐ PI Change ☐ Title Change
☐ Response to Committee's Concerns ☐ Other _____

DO NOT WRITE BELOW THIS LINE

2.0 Expedited review of minor change in approved research [45 CFR 46.110(b)]

- ☒ N ☐ Y Risks to subjects increased ☒ Y ☐ N ☐ N/A Consent form satisfactorily revised
☒ Approve ☐ Approve w/notation ☐ Approval cannot be granted (Requires full Board review)
☐ Approve pending satisfactory response — ☐ Member review ☐ Administrative review

3.0 Other: ☐ IRB Notified; Approval Not Required

Comments: will notify Supr to inform of research
value of helping research

The signature of the IRB Chair/Designate and IRB approval stamp on this form will serve as documentation of IRB review and approval of the attached item(s).

Signature of IRB Chair/Designate Ira Wollner, M.D. Date 10/21/98

☐ Item will be reviewed as an information item at the next regularly scheduled IRB meeting.
Date of Amendment/Revised Consent Form Approval: _____





Center for Medical Treatment Effectiveness Programs
1 Ford Place, Suite 3E, Detroit, MI 48202 (313) 874-1890 Fax (313) 874-6944



To: Ira Wollner, MD, Chair, HFHS Human Rights Committee

From: Marvella Ford, PhD *MF*

Subject: Request for Amendment to the Human Rights protocol of the Research Proposal
"African American Men in the PLCO Trial: Developing and Testing Methods to
Increase Retention"

Date: October 19, 1998

Thank you for reviewing and approving the protocol for the above-referenced research project. I am writing to request an amendment to this protocol. The intervention in this project is entirely telephone-based and requires no face-to-face contact with the study participants. Therefore, individuals can indicate their consent to participate in the study by verbally agreeing to be called on a monthly basis by the retention coordinator.

Potential participants will be informed during an introductory telephone call that they will not receive a penalty or loss of benefits of any sort based upon their decision to participate in the study. They will also be informed that their decision to participate will not affect the medical care they receive from their usual source (see attached telephone script). The research activities in this proposal involve no more than minimal risk and the involvement of human participants will be within the categories enumerated in 45 CFR 46.110 (a) (b): 1-10.

This research project has been recommended for funding by the Department of Defense. I look forward to hearing from you soon regarding this matter. If you have any questions or need additional information, please call me at (313) 874-5433.

Ira Wollner, MD, Chair, HFHS Human Rights Committee

Page 2

October 19, 1998

SCRIPT FOR INTRODUCTORY TELEPHONE CALL

Hello, is this _____? My name is _____. I have been assigned to assist you in receiving your screenings as part of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. I would like to call you on a monthly basis to :

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request. I would like to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial.

Ira Wollner, MD, Chair, HFHS Human Rights Committee

Page 3

October 19, 1998

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Thank you very much for your time. I look forward to talking with you in the future.



Center for Medical Treatment Effectiveness Programs
1 Ford Place, Suite 3E, Detroit, MI 48202 (313) 874-1890 Fax (313) 874-6944



To: Ira Wollner, MD, Chair, HFHS Human Rights Committee

From: Marvella Ford, PhD *MF*

Subject: Request for Expedited Review of the Research Proposal "African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention"

Date: August 27, 1998

I am requesting expedited review and waived consent for the above-referenced research project because the research activities in this proposal involve no more than minimal risk and the involvement of human participants will be within the categories enumerated in 45 CFR 46.110 (a) (b): 1-10.

This research project has been recommended for funding by the Department of Defense. The DOD has requested that a Protection of Human Subjects Form, which will be signed by Ms. Marsha Kelter upon your review and approval of the attached materials, be sent to them as soon as possible.

I look forward to hearing from you soon regarding this matter. If you have any questions or need additional information, please call me at (313) 874-5433.

HENRY FORD HEALTH SYSTEMS HUMAN RIGHTS COMMITTEE TRANSMITTAL FORM
(PLEASE TYPE OR NEATLY PRINT IN BLACK INK)

I. General Information

1. Project Title		African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention			
2. Principal Investigator (Name/Degree/Title)		Associate Staff Marvella E. Ford, Ph.D. Investigator			
Department	Center for Medical Treatment Effective Division ness Prg. in Diverse Populations	-	Phone/Pager	-	-
3. Contact Person (Name/Degree/Title)		Associate Staff Marvella E. Ford, Ph.D. Investigator			
Department	-	Division	-	Phone/Pager	-
4. Grant Title & Project Director (if different)					
5. Sponsor/Funding Source (name of agency, company, NIH Institute or internal committee that will fund/sponsor the research)			Department of Defense		
6. Date Submitted to Funding Agency			October 28, 1997		
7. Multicenter study?		<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	8. Proposed Project Period	
				10/01/98 - 03/31/01	
9. Performance Site(s):	Detroit <input checked="" type="checkbox"/>	Fairlane <input type="checkbox"/>	Lakeside <input type="checkbox"/>	Troy <input type="checkbox"/>	West Bloomfield <input type="checkbox"/>
<input type="checkbox"/> Other (specify):					
10. Research to be conducted:	Inpatient <input type="checkbox"/>	Inpatient/Outpatient <input type="checkbox"/>	Outpatient <input checked="" type="checkbox"/>	<input type="checkbox"/> Other (specify):	

II. SIGNATURES

11. The undersigned accepts responsibility for assuring that the protocol will be conducted in adherence to all applicable FDA and HHS regulations and Institutional Policies relative to the protection of the rights and welfare of human subjects.	SIGNATURE OF PRINCIPAL INVESTIGATOR	DATE
	<i>Marvella E. Ford</i>	8-27-98
12. As Division Head (Where there are no divisions, Chairman of the Dept.), the undersigned has reviewed and supports the scientific merit of the attached protocol and its submission to the Human Rights Committee. The principal investigator is qualified to conduct the study and the resources necessary to perform the study are available.		
PRINT OR TYPE NAME OF DIV HEAD/DEPT CHAIR/MED DIR	SIGNATURE	DATE
Barbara C. Tilley, Ph.D.	<i>Barbara C. Tilley</i>	8/27/98

DO NOT WRITE BELOW THIS LINE

HRC APPROVAL STAMP	PROTOCOL APPROVAL (TO BE COMPLETED BY HUMAN RIGHTS COMMITTEE)		
	<input type="checkbox"/> Full Board Review	<input type="checkbox"/> Expedited Review	<input type="checkbox"/> Exempt
	Period of Approval _____		
	IRB Ref. # _____	Accession No. _____	
	Signature of HRC Chairperson _____		

V. DESCRIPTION OF PROTOCOL POPULATION AT HFH

16. Protocol Population (✓ all that apply)	Age Range	Number	Source
<input checked="" type="checkbox"/> Adult Subjects (≥ 18 years)	55-74	450 + 20 (focus groups)	PLCO intervention arm screeners and HFHS patient population
<input type="checkbox"/> Minor Subjects (<18 years)*			
<input type="checkbox"/> Women of Conceptive Capability			
<input type="checkbox"/> Men of Conceptive Capability			
<input type="checkbox"/> Pregnant Women*			
<input type="checkbox"/> Cognitively Impaired Persons*			
<input type="checkbox"/> Mentally Retarded Persons*			
<input type="checkbox"/> HFH Employees/Students			
<input type="checkbox"/> No Subjects, Data Review			
<input type="checkbox"/> Other, Specify (describe below)			

* - The applicant should provide clear rationale for including these populations.

VI. RECRUITMENT

17. Total number of subjects in study	450 + 20 (focus groups)	18. Total number subjects at HFH	20
19. How will population be recruited (provide, on attached sheet, a copy of any proposed information to be disseminated)			
<input type="checkbox"/> Advertisement (attach copy)	<input checked="" type="checkbox"/> Letter (attach copy)	<input type="checkbox"/> Patient Visit	
<input checked="" type="checkbox"/> Telephone (attach script)	<input type="checkbox"/> Other		

VII. TIME COMMITMENT

20. Number of visits	a) Outpatient:	3	b) Inpatient:	
21. Average duration of visits	1 Hour	23. Total duration of individual's participation	3 visits at 1 hour each	

HENRY FORD HOSPITAL HUMAN RIGHTS COMMITTEE
DRUG/SUBSTANCE INFORMATION - FORM A

PROJECT TITLE:

PRINCIPAL INVESTIGATOR:

NOTE: This form must be completed for each individual drug or substance (investigational or marketed) which is being administered as part of this research study.

1. GENERIC OR CHEMICAL NAME:

2. TRADE NAME:

3. MANUFACTURER:

4. MODE OF ADMINISTRATION:

5. HOW SUPPLIED (DOSAGE FORM + STRENGTH):

6. WHO IS TO ADMINISTER THE DRUG/SUBSTANCE?

7. DOSAGE AND SCHEDULE PROPOSED:

8. DESCRIBE THE PRIMARY ACTIONS OF THE DRUG/SUBSTANCE:

9. DESCRIBE THE THERAPEUTIC BENEFIT ANTICIPATED FROM THE USE OF THIS DRUG/SUBSTANCE:

10. LIST THE KNOWN SIDE EFFECTS OF THIS DRUG/SUBSTANCE AND THEIR ANTICIPATED INCIDENCE:

11. DESCRIBE THE PRECAUTIONS USED TO INSURE THAT THE RISKS ASSOCIATED WITH THE ADMINISTRATION OF THIS DRUG/SUBSTANCE IS MINIMIZED:

HENRY FORD HOSPITAL HUMAN RIGHTS COMMITTEE
DEVICE INFORMATION - FORM B

PROJECT TITLE:

PRINCIPAL INVESTIGATOR:

NOTE: This form must be completed for each individual device (investigational or marketed) which is being used as part of this research study.

1. NAME OF DEVICE:

2. MANUFACTURER:

3. MARKETING: YES ☐ NO ☐ (IF 510K RECEIVED, INCLUDE FDA DOCUMENTATION)

4. INVESTIGATIONAL: YES ☐ NO ☐
IF YES, IDE# _____ (INCLUDE FDA DOCUMENTATION)

5. WILL DEVICE BE PROVIDED FREE OF CHARGE FOR THE STUDY? YES ☐ NO ☐

IF NO, WHO WILL BE RESPONSIBLE FOR DEVICE COSTS:

IF THE SUBJECT (OR SUBJECT'S HEALTHCARE INSURER) WILL BE CHARGED FOR THE DEVICE,
WHAT ARE THE COSTS OF DEVICE?

6. IS THE DEVICE IMPLANTED OR OTHERWISE PLACED INTO THE BODY? YES ☐ NO ☐
EXPLAIN:

IF YES, MUST THE DEVICE BE REMOVED FROM THE BODY AFTER THE STUDY? YES ☐ NO ☐

WHO WILL BE RESPONSIBLE FOR PLACEMENT IN AND REMOVAL FROM THE BODY?

7. IS WARRANTY AVAILABLE? YES ☐ NO ☐
(INCLUDE COPY OF WARRANTY WITH APPLICATION)

8. THE APPLICATION TO THE HUMAN RIGHTS COMMITTEE SHOULD INCLUDE ALL AVAILABLE
INFORMATION ON THE DEVICE INCLUDING MANUFACTURER'S BOOKLET, DIAGRAMS, PROMOTIONAL
MATERIALS, ETC.

HENRY FORD HOSPITAL HUMAN RIGHTS COMMITTEE
Application for Investigational Procedures in Humans Involving Radiation - FORM C

Project Title:

Principal Investigator:

1. Identify the source of radiation exposure to the patient/subject. [Check all that apply.]

☐ Radioactive Materials

☐ Diagnostic X-Ray

☐ Therapeutic Radiation Machine

☐ Other (describe):

[NOTE: If an investigational radioactive drug is used the HRC may approve the Human Rights aspects of the project. However, the project cannot begin and subjects may not be enrolled until notification of Radiation Safety Committee approval is received and accepted by the HRC.]

2. Location/facility where the procedure will be performed:

3. Are the procedures to be performed administered within the "standard of care" for the patient's/subject's condition? In other words, would the patient receive these procedures even if he/she were NOT a research subject for this protocol?

☐ Yes (go to IV)

☐ No (go to V)

4. CLINICAL CARE (Describe the procedures performed as a "standard of care" that result in radiation exposure to the patient)

Procedure	Machine/Radioactive Agent	Total #	Area of Body, Views	Frequency

5. RESEARCH (Describe the additional procedures resulting in radiation exposure to the patient)

Procedure	Machine/ Radioactive Agent	Total #	Area of Body, Views	Frequency	Dose per Procedure*	Total Dose*

* - Specify entrance exposure for diagnostic x-rays; absorbed dose for others.

6. Describe benefit of the radiation exposure in comparison to its risk.

Henry Ford Hospital

CONSENT
TO PARTICIPATE IN A RESEARCH STUDY

☐ MAIN

☒ WEST BLOOMFIELD

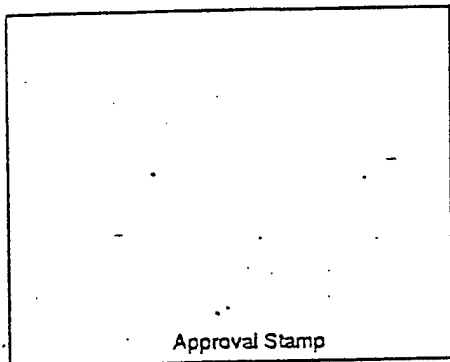
☐ FAIRLANE

☐ OTHER _____

DATE

MRN

NAME



Approval Stamp

PROJECT TITLE:

SUBMIT ONLY ONE ORIGINAL (DO NOT COPY)

HUMAN RIGHTS COMMITTEE APPLICATION COMPLETION CHECKLIST

PRINCIPAL INVESTIGATOR: Marvella E. Ford, Ph.D.

PROTOCOL TITLE: African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention

TO ENSURE THAT YOUR APPLICATION IS COMPLETE AND TO IMPROVE ITS REVIEW AT THE HUMAN RIGHTS COMMITTEE MEETING, PLEASE FILL OUT THE FOLLOWING CHECKLIST. ONE COPY OF THIS CHECKLIST MUST BE RETURNED WITH YOUR HUMAN RIGHTS COMMITTEE APPLICATION. THE APPLICATION WILL NOT BE PROCESSED WITHOUT RECEIPT OF THIS CHECKLIST.

	<u>PROVIDED</u>	<u>NOT</u> <u>APPLICABLE</u>	<u>EXPLANATION</u>
ABSTRACT	<input checked="" type="checkbox"/>	→→→→→→	
SIGNATURES	<input checked="" type="checkbox"/>	→→→→→→	
RATIONALE FOR SPECIAL POPULATIONS	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
ADVERTISEMENT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
LETTERS OF COMMITMENT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
IND/IDE #	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
METHOD TO ENSURE EXCLUSION OF PREGNANT WOMEN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
INFORMED CONSENT PROCESS DESCRIPTION	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
COMPLETED CONSENT FORM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

(NOTE: FOR ANY ITEMS DUE BUT NOT INCLUDED WITH THE APPLICATION, YOU MUST PROVIDE AN EXPLANATION.)

IN ADDITION, FOR YOUR OWN BENEFIT AND TO ASSIST IN THE EFFICIENT PROCESSING OF YOUR APPLICATION, PLEASE CHECK THE FOLLOWING ITEMS:

HAS THE CONSENT BEEN PROOFREAD FOR TYPOGRAPHICAL AND GRAMMATICAL ERRORS?

IS THE CONSENT FORM WRITTEN IN THE SECOND PERSON FORMAT AS REQUIRED (I.E., YOU, YOUR)?

ARE THE PAGES OF THE CONSENT FORM CORRECTLY NUMBERED?

HAS THE PROPER APPROVED CONSENT FORM BEEN USED? (FORM 5405 MR REV. 2/94, WITH APPROVAL BOX ON EACH PAGE)

HAVE BOTH SIDES OF THE APPLICATION/CONSENT FORM BEEN COPIED? ARE ALL PAGES COLLATED AND STAPLED IN CORRECT ORDER?

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

PROTOCOL

PROJECT TITLE. African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention

LOCATION OF STUDY. Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

TIME REQUIRED TO COMPLETE. Month/year of expected start: October 1, 1998. Month/year of expected completion date: March 31, 2001.

STUDY OBJECTIVES. The specific aims of the proposed study are to evaluate the efficacy of a retention intervention in retaining African American men in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, and to develop a culturally appropriate measurement instrument to assess perceptions of screening for these cancers among older African American men. The intervention consists of assigning men in the screening arm of the PLCO trial to a retention coordinator who will provide intensive follow-up, guide them through the PLCO Trial processes, and serve as an information clearinghouse for other health and social services needs the participants may have.

HYPOTHESES. It is hypothesized that, among African American men enrolled in the screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial at the Henry Ford Health System site, those randomized to receive an intensive follow-up intervention provided by a retention coordinator will show higher retention rates than men in the control group. Retention is defined as adherence to the PLCO Trial screenings.

SIGNIFICANCE OF THE STUDY. The findings from this feasibility study will lay the foundation for a future trial of an innovative retention intervention (if successful, or modified if necessary) in cancer screening trials. In the future trial, the developed measurement instrument could be used to assess differences in knowledge, attitudes, and beliefs about cancer screening in a cohort of men, and to help identify potential study drop-outs, for whom more intensive interventions may be necessary in order to reduce attrition. In addition, the intervention could be tailored to African American men of varying socio-demographic characteristics. The findings from this study can be used to help African American men benefit from one of the positive aspects of involvement in cancer screening clinical trials: early detection or prevention of cancer.

PLAN.

Inclusion Criteria, Selection of Subjects, Number of Subjects, Age Range, Sex, Source of Subjects, Subject Assignment: Participants in the longitudinal PLCO Trial must be asymptomatic of the four PLCO Trial cancers upon randomization to the PLCO Trial. The 458 African American men ages 55 and over currently enrolled in the screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial at the Henry Ford Health System site will be randomly assigned to a retention coordinator intervention group or to a control group.

The retention coordinator will then receive a listing of the 229 men assigned to the intervention group, as well as their screening status. Their screening status will include the following information: the date, time, and location of their next screening appointment, whether they kept their previous appointment, and the type of screening they will have next (whether it is a baseline screening or a time one, two, or three screening). All of this information is available at the Henry Ford Health System PLCO Trial site. Participants are identified by a numeric code.

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

The retention coordinator will be responsible for scheduling PLCO Trial screening appointments for the men assigned to the intervention. He or she will then provide intensive follow-up to these men, and will serve as a source of informational and emotional social support. Follow-up will be made in the following areas, suggested by Womeodu and Bailey¹ as being steps to successful cancer screening. These steps include: (1) helping to assure that the participants are able to keep their screening appointments. This step may involve working with local public and private services to help the participants find available transportation, and giving the participants detailed directions to the clinic where the screening will take place; (2) answering questions about the screening procedures. The retention coordinator can verbally guide the participants through the screening procedures ahead of time, so that the participants will know what to expect when they arrive for screening; (3) helping the participants to understand the sometimes complex and detailed instructions about preparing for screening procedure(s); (4) calling the participants to remind them of their scheduled appointments; and (5) calling the participants if the screening appointment was not kept, to ascertain the reason and to help with possible difficulties in keeping the appointment. In addition, the retention coordinator will assist the participants with other health and social services needs they may have by serving as a clearinghouse for information related to these needs. If a participant has a question about a particular health or social service, and the information is not readily available to the retention coordinator, he or she will make a concerted effort to locate the pertinent information, and will re-contact the participant once the information has been found, to share the information with the participant. The retention coordinator will be expected to speak with each PLCO Trial participant in the intervention group at least once per month, and more frequently if the participant's screening appointment is approaching. Prior to beginning the intervention, the retention coordinator will be trained in the PLCO Trial screening procedures, and will also contact local health and social services organizations providing services to older adults, to receive information about programs and services available to members of this group.

Individuals are required to list a contact telephone prior to their enrollment in the PLCO Trial at the Henry Ford Health System site. However, in the event of a person having a disconnected telephone number, a number of tracking strategies currently used in the PLCO Trial will be used by the retention coordinator. These tracking strategies include the use of a CD-ROM containing White Page listings of residences in the United States, and two Internet programs: Switchboard Directory and Whowhere Directory.

In terms of the focus groups held to assist in the development of a culturally appropriate psychosocial instrument (questionnaire) designed to measure perceptions of cancer screening among older African American men, each focus group will consist of men who are homogenous in age and race/ethnicity, as is typical for focus group participants. Our focus groups will typically be composed of 7 to 10 African American men who are representative of the target population of African American men aged 55-74. Potential focus group participants, who are not PLCO Trial participants, will be randomly selected from the Henry Ford Health System patient population using demographic information contained in the computerized patient information in the Henry Ford Health System Corporate Data Store. Identified men will then be contacted by telephone by the investigators and screened for theoretical eligibility to participate in the PLCO Trial. If the men are found to be theoretically eligible to participate in the PLCO Trial, they will then be recruited, via an invitation letter and a follow-up telephone call by the investigators, to participate in the focus groups, until the maximum number of focus group participants has been reached. Each man will participate only once in a focus group.

Risks to the Subject, Precautions to be Taken to Minimize/Eliminate Risks, and Use of Information/Publications Arising from the Study: The risks of participating in this project are minimal. The research activities in this proposal involve no more than minimal risk the involvement of human participants, which is within the categories enumerated in 45 CFR 46.110 (a) (b): 1-10. The retention coordinator intervention involves neither invasive nor intrusive procedures. All telephone contact will be conducted in a professional manner. Consent

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

forms will be mailed to all participants assigned to the retention coordinator intervention. Should a participant explicitly state, at any time during the research project, that they do not wish to be contacted in the future, their request will be honored. Likewise, should an individual contacted by the investigators to participate in a focus group decline to do so, their request will be honored. In terms of study confidentiality, all study staff have been or, in the case of the to-be-named retention coordinator, will be, trained to appreciate the confidential nature of epidemiological and clinical data. Study personnel will be required to annually sign a standard confidentiality policy (see attachment). All identifying information will be handled with the highest degree of discretion and confidentiality. Results from this research will be reported only as statistical aggregates. Individual-level data will not be presented.

In terms of data quality assurance, detailed consistency checks across forms and files will be conducted. A subsample (5%) of telephone interview respondents will be randomly called to verify the fact that they were contacted by the retention coordinator.

Role of the Principal Investigator: In addition for designing and having overall responsibility for the integrity of the proposed study, the Principal Investigator, in conjunction with the Consultant, will develop a culturally appropriate measurement instrument to assess cancer screening knowledge, attitudes, and beliefs among African American men. Initially, literature searches will be conducted as a means of identifying existing instruments assessing attitudes toward cancer screening and other relevant constructs. For each instrument identified, the following questions will be addressed. These questions reflect work conducted by McDowell and Newell:² (1) on which population(s) was the instrument tested? (Ex: Caucasians, men, college students, etc.); (2) to which population(s) has the instrument been applied since its original publication?; (3) what are the reliability coefficients of the instrument components or the overall reliability of the instrument, by population?; (4) in what ways has the instrument been validated?; (5) is the instrument self- or professionally-administered?; (6) what is the average length of time for completing the instrument?; (7) what is the conceptual approach to the topic area (such as psychological well-being)?; (8) has the instrument been tested in older populations?; (9) is this conceptual approach relevant to/appropriate for African Americans, particularly those in the same age group as PLCO participants (55-74)?; and (10) is the original purpose of the instrument appropriate for use in the proposed study?

Once a defined set of questions has been developed/identified, two focus groups will be held. The focus groups will be used to examine the perceptions of African American men toward cancer screening, and to develop questions about cancer screening that are culturally tailored to members of this group. The results of the first focus group are expected to lead to refinement of the measurement instrument, which will then be tested in a second focus group. Thus, the focus groups will be used to help develop a culturally appropriate instrument that can be used in future trials to measure perceptions of cancer screening among older African American men.

Roles of the Biostatistician and Data Manager: The biostatistician will be responsible for overseeing the statistical considerations of the proposed retention study. For example, in terms of statistical considerations for the retention coordinator intervention, the biostatistician will take into account the following areas:

Justification of Sample Size. There were 915 African American men randomized to the Henry Ford Health System site of the PLCO Cancer Screening Trial as of 10/16/97. Of the 915 men, approximately 450 have been randomized to the intervention (screening) arm of the PLCO Trial. These 450 men, who will serve as the cohort for the proposed feasibility study, will be assigned a socioeconomic status code by the biostatistician, who will then randomize the men to the retention intervention group or to a control group. Based upon the work of Kelly and Shank,³ we have estimated our adherence rate for flexible sigmoidoscopy to be 30%. The screening for colorectal cancer is the most invasive screening for men in the screening arm of the PLCO Trial. If participants refuse screening for colorectal cancer, they may refuse screening for the other cancers as well. Thus,

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

the adherence rates for the other PLCO cancer screenings may be similar to or higher than the adherence rates for colorectal cancer screening. If the final sample size is 450, with 225 men in each arm, there will be 90% power to detect an increase in adherence rate of 15%, assuming 30% adherence in the control arm. Power calculations were based on two-sided testing with an alpha of 0.05. If the adherence rate in the control group is actually only 20% then there will be 90% power to detect a 13% increase in adherence rate. If the adherence rate in the control group is actually 40% then there will still be 90% power to detect a 15% increase in adherence rate. For within-socioeconomic status (SES) strata comparisons, the power calculations change based on the percentage of the group falling into each of the two SES strata. If there is a 50% split between low and moderate to high SES group, there will be 90% power to detect a 33% change in adherence rate, assuming 30% adherence rate in the control group. If there is a 40/60% split, which is currently the trend among African American men at the HFHS site of the PLCO Trial, there will be 90% power to detect a 36% change in the smaller SES sub-group and 90% power to detect a 30% in the larger SES sub-group. All power calculations for within SES strata have assumed a type I error of 2.5% to adjust for multiple comparisons within strata.

Planned Data Analysis for the Retention Intervention. Adherence rates between the two groups will be compared using a Mantel-Haenszel test, with SES as the strata. A test of homogeneity of the odds ratio will be assessed and if the strata are found to be homogenous the strata will be combined (but strata always included as a covariate), otherwise the testing will be performed separately for each strata. Testing will be two-sided and assume a type I error of 5% for the overall group and a type I error of 2.5% for within strata comparisons. The secondary outcome of cost will be compared using standard linear regression with an indicator variable for SES strata as a covariate, if the underlying assumptions are met. It is possible that the cost data may need to be transformed or non-parametric testing may need to be pursued in order to correctly analyze the data. All underlying assumptions for each test will be verified.

The data manager will provide data management support for the proposed study, and will be responsible for the accuracy and integrity of data after collection. The data manager will monitor the database, run edit checks, consistency checks and monitoring reports. In order to use the study data to write manuscripts and develop grants it is essential that the data be well organized and edited and accessible for statistical analysis. The data manager will establish study files and keep master lists of participants.

Strengths of the Proposed Research: The proposed study focuses on older men, who are more likely than younger men to be affected by prostate cancer. Thus, the results of the retention study will add to existing knowledge of factors influencing adherence to prostate cancer screening among men who as a group are significantly affected by this disease, and can also shed light on ways of measuring perceptions of prostate cancer screening in members of this group. Because the PLCO Screening Trial is a large, ongoing study, the retention intervention can have a long-term effect on retaining African American men in the PLCO Trial. A major strength of this study is that if the retention intervention is found to have a substantial impact on retaining African American men in the PLCO trial at the Henry Ford Health System site, the intervention could be integrated into the PLCO Trial as a standard retention procedure with members of this population in other PLCO Trial sites as well. Another strength of this feasibility study is that it can serve to enrich the sample of African American men in the PLCO trial, and can serve as a model to increasing their retention in other types of cancer screening trials. An additional strength of the proposed retention study is the fact that it will be carried out in the Detroit metropolitan area. Because this area is demographically representative of other large, urban areas, our results on successful retention strategies will be generalizable to other geographic areas as well. The Detroit metropolitan area, which has a large number of African Americans, is socioeconomically diverse, which permits an examination of the effects of socioeconomic status on the intervention outcomes. A distinct advantage to carrying out the retention study through the Henry Ford Health System is the rich array of available technical resources. In summary, the risks to the participants in the proposed recruitment trial are

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

minimal, while the benefits are extremely far-reaching.

Personnel to Conduct the Project:

Principal Investigator/Behavioral Scientist - Marvella E. Ford, Ph.D., (yr 1 - 20%, yr 2 - 20%, yr 3 - 20%)

Dr. Marvella Ford, an Associate Staff Investigator with the Henry Ford Health System (HFHS) Center for Medical Treatment Effectiveness Programs (MEDTEP), has experience in the area of psychosocial factors affecting the use of health services among African Americans. Dr. Ford has received pre- and post-doctoral fellowships from the National Institute on Aging and is committed to studying issues related to older African Americans. She has given numerous conference presentations on this topic. Two of her writings, "Health Services Use among African Americans: A Beginning Look at the Effects of Perceived Control" and "The Black Oldest Old: Age and Physical Functioning", co-authored with Dr. Rose C. Gibson, (Editor-in-Chief of *The Gerontologist*), were based on data from the National Survey of Black Americans.

Dr. Ford is actively involved in the development of culturally relevant data collection instruments and outcome measures from a psychosocial perspective. At the present time, she is serving as co-investigator on an NCI/CDC-funded trial designed to increase the recruitment of African American men into the prostate, lung, and colorectal components of the Prostate, Lung, Colorectal, and Ovarian Cancer (PLCO) Screening Trial currently being conducted in the Henry Ford Health System (AAMEN Project). She is also Assistant Professor of Epidemiology and Biostatistics at Case Western Reserve University, Community Associate with the Institute of Gerontology at Wayne State University, a faculty member in the Community Oriented Primary Care Program at HFHS, a board member of Southwest Detroit Community Mental Health Services, Inc., a social service agency in Detroit, and was recently appointed Adjunct Assistant Professor in the Department of Psychology at Wayne State University.

Dr. Ford will direct and assume overall responsibility for the retention trial. She will oversee the daily activities of the retention intervention and measurement instrument development aspects of this research, the interpretation of results, and manuscript preparation and submission. Dr. Ford will conduct regular meetings with study staff to ensure the smooth flow of this study.

Co-Investigator/Epidemiologist - Christine Cole Johnson, Ph.D., (yr 1 - 5%, yr 2 - 5%, yr 3 - 5%)

Dr. Christine Johnson, Co-Principal Investigator on the NCI PLCO Cancer Screening Trial, will serve as a link between the proposed trial and the PLCO trial. Dr. Johnson, who is the Associate Director for Research at the Henry Ford Health System (HFHS) Cancer Center, will serve as a Co-Investigator in the interpretation and publication of results. Her training and experience in clinical epidemiology and follow-up studies qualify her for these roles. As Co-Principal Investigator on the NCI PLCO Cancer Screening Trial, Dr. Johnson has direct responsibility for overseeing the follow-up of the 20,000 HFHS respondents to be enrolled in the PLCO Trial at the HFHS site.

Dr. Johnson also currently directs the data collection components of an EPA funded pilot study of lung cancer in non-smokers identified by the SEER registry and radon exposure, and an NIEHS funded case-control study of Parkinson's disease and occupation. She is an adjunct scientist at the Michigan Cancer Foundation, was formerly a member of a board overseeing a statewide breast and cervical cancer screening program, and is a member of the Michigan Prostate Cancer Consensus Conference. Dr. Johnson was the senior epidemiologist on a study of colon cancer in General Motors pattern and model makers and serves on the advisory committee to the NCI funded worksite intervention research that HFHS conducted at GM worksites (PI: B.C. Tilley, HFHS). Dr. Johnson will attend regular meetings with the research staff. She brings with her expertise in the area of conducting large, randomized controlled cancer screening trials. Dr. Johnson's time spent on this project will be supported by the PLCO Trial.

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

Retention Coordinator - TBN, (yr 1 - 50%, yr 2 - 50%, yr 3 - 50%)

The retention coordinator will intervene with a sample of men successfully recruited and randomized to the intervention arm of the PLCO trial. He or she will call the men to let them know she/he is available to be called if they have questions or concerns about the study or have health-related questions, and will schedule PLCO cancer screening appointments for the men in the retention intervention group. He or she will also serve as an information source for these questions, providing the men with the names and telephone numbers of community health care professionals who can respond to the questions. If men call with questions about the study, the retention coordinator will answer their questions or refer the caller to an appropriate person to get their questions answered. In the final two months of the study, he or she will contact the men in the intervention group to let them know that he or she will no longer be calling, and to answer any final questions the men might have. Because the retention coordinator will schedule PLCO cancer screening appointments for men assigned to this intervention, an additional 25% percent effort on the study will be supported by the PLCO Trial, for a total of 75% effort.

Biostatistician - Suzanne Havstad, M.S., (yr 1 - 10%, yr 2 - 10%, yr 3 - 15%)

Ms. Havstad is a biostatistician who has experience working with large databases and complex statistical problems. She has over eight years of experience in a biostatistical consulting environment. Ms. Havstad will execute statistical analyses for the retention project.

Data Manager - Diane Moore, (yr 1 - 15%, yr 2 - 15%, yr 3 - 10%)

Ms. Moore will provide data management support. Ms. Moore has experience as a data manager on several National Institutes of Health funded trials. She will assure that the appropriate data management procedures are in place. She will also be responsible for the accuracy and integrity of data after collection. Ms. Moore will monitor the database, run edit checks, consistency checks and monitoring reports. In order to use the study data to write manuscripts and develop grants it is essential that the data be well organized and edited and accessible for statistical analysis. Ms. Moore will establish study files and keep master lists of participants.

Data Entry - Deborah Greene (yr 1 - 14%, yr 2 - 12%, yr 3 - 15%)

Ms. Greene will enter the data for the proposed study.

Secretary - Lynn Merrill, (yr 1 - 15%, yr 2 - 10%, yr 3 - 10%)

Ms. Merrill will provide all clerical support to the study. She will be responsible for typing the manual of procedures, forms, manuscripts, technical reports, and other documents for study staff. Ms. Merrill will also answer telephones, copy articles, maintain the study's bibliographic file and library, and schedule meetings.

CONSULTANT

Consultant - Sally Vernon, Ph.D.

Dr. Sally Vernon, Professor of Behavioral Sciences and Epidemiology at University of Texas Health Science Center, will serve as a consultant to the proposed study. Her work focuses on factors associated with participation in cancer screening. Dr. Vernon has expertise in the development of measurement instruments related to perceptions of cancer screening. She will assist Dr. Ford in the operationalization of the retention intervention, will consult about its implementation, and participate in the data analysis to evaluate the impact of the intervention. She will also participate in the development of a knowledge, attitudes, and beliefs questionnaire about cancer screening that can be evaluated and used in a subsequent study. Dr. Vernon will be available for 10 days in each of years 1 and 2 and for 6 days in the first half of year 3. She will travel to Detroit

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

to consult with the study investigators once per year during the 2 ½ years of the study.

"I have read the foregoing protocol and agree to conduct the study as outlined herein."

Marvella E. Ford, Ph.D.,
Principal Investigator

Date

Approving Official

Date

Principal Investigator: Marvella E. Ford, Ph.D., Case Western Reserve University, Henry Ford Health Sciences Center, 2799 West Grand Blvd. Detroit, MI (313) 874-5433.

Bibliography

1. Womeodu, R. and Bailey, J. Barriers to cancer screening. *Medical Clinics of North America*, 80: 115-133, 1996.
2. McDowell I, Newell C. Measuring Health: a guide to rating scales and questionnaires, In: 1996:
3. Kelly, R.B. and Shank, J.C. Adherence to screening flexible sigmoidoscopy in asymptomatic patients. *Med Care*, 30: 1029-1042, 1992.

Henry Ford Hospital

CONSENT FORM A
TO PARTICIPATE IN A RESEARCH STUDY

☐ MAIN☐ WEST BLOOMFIELD☐ FAIRLANE☐ OTHER _____

DATE

MRN

NAME

PROJECT TITLE:

African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention

Approval Stamp

I. Purpose of the Research: I have been asked to take a part in a research project sponsored by the Department of Defense. The purpose of this study is to identify and innovative way to retain African American men in prostate cancer research studies.

II. Project Plan: I understand that by agreeing to participate in this study over the next 24 months, I will be contacted at least once per month by study staff. If I request, I may be contacted more often than once per month. Each telephone call will last a minimum of ten minutes. I have the right to end the telephone call at any point. I understand that the staff member who calls me will assist me in keeping my PLCO screening appointments. This staff member will give me detailed directions to the PLCO screening clinic. The staff member will also help me to find transportation if I need it. Also, if I would like assistance with other areas of my life, the staff member will help me to locate resources.

III. Risk of the Project: There are no expected risks to me from taking part in this project.

IV. Benefits of the Project: I understand that by taking part in this study, I will have the chance to talk with a staff member at least once per month. This staff member can help explain the PLCO screening process to me, and can assist me in getting to the PLCO screening site. Questions I have regarding health or social services needed by me or a family member will also be answered by the staff member.

V. Costs of the Project: I understand that I will not be asked to pay any costs associated with this study.

VI. Voluntary Participation: I know that I don't have to be a part of this project. I can decide not to take part at the beginning or I can start and then decide to stop. Whatever I decide, I will not receive a penalty or loss of benefits of any sort based upon my decision. My decision will not affect the medical care I receive from my usual source.

VII. Privacy: I understand that information about my participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal information such as name, address, and social security number will be used to identify me once the project has ended in two years.

VIII. Points of Contact: I know that I can call Dr. Ford at (313) 874-5433 for more information about this project. If I am injured as a result of being in this project, I should call Dr. Ford at (313) 874-5433.

Henry Ford Hospital

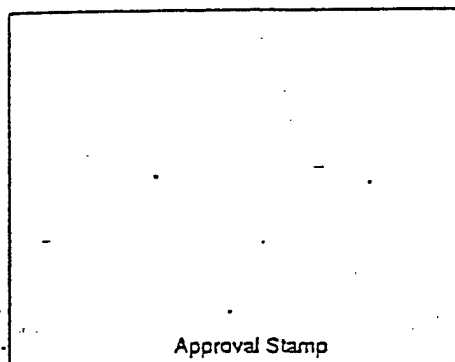
CONSENT FORM B
TO PARTICIPATE IN A RESEARCH STUDY

☐ MAIN☐ WEST BLOOMFIELD☐ FAIRLANE☐ OTHER _____

DATE

MRN

NAME



PROJECT TITLE:

African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention (For Focus Group Participants)

I. Purpose of the Research: I have been asked to take a part in a research project sponsored by the Department of Defense. The purpose of this study is to develop a culturally appropriate questionnaire to assess perceptions of cancer screening among African American men in the PLCO Trial using the results of focus groups of older African American men.

II. Project Plan: I have been asked to take part in a focus group. A focus group involves an in-depth discussion of a particular topic. In the focus group, I will share my thoughts about cancer screening, and will help to develop questions about cancer screening. Each focus group will be composed of about 10 African American men ages 55 and older.

III. Risk of the Project: There are no expected risks to me from taking part in this project.

IV. Benefits of the Project: I understand that by taking part in this study, I will have the chance to share my thoughts regarding cancer screening. I will also be able to hear what other African American men think about this topic.

V. Costs of the Project: I understand that I will not be asked to pay any costs associated with this study.

VI. Payment: I understand that I will be paid for taking part in the focus group. I may also receive transportation to the focus group, if I request it.

VII. Privacy: I understand that information about my participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal information such as name, address, and social security number will be used to identify me once the project has ended in two years.

VIII. Points of Contact: I know that I can call Dr. Ford at (313) 874-5433 for more information about this project. If I am injured as a result of being in this project, I should call Dr. Ford at (313) 874-5433.

If I have questions about my rights as a research participant I may contact Ms. Nancy Thayer in the Research Office at Henry Ford Hospital at (313) 876-2024. I will be informed about important new information that comes from this project.



HENRY FORD HEALTH SCIENCES CENTER

Research Administration

CFP-1
2799 West Grand Boulevard
Detroit, MI 48202-2689
(313) 916-2024 Office
(313) 916-2018 Fax

Thomas Roth, PhD
Director of Research

Lynne M. Pease, MHA
Administrative Director
of Research

S. David Nathanson, MD
Chair, Care of Experimental
Animals Committee

Ira Wollner, MD
Chair, Human Rights Committee

Leonard Lutter, PhD
Chair, Small Projects
Funding Committee

October 16, 1998

TO: Marvella Ford, Ph.D
Center for Medical Treatment Effectiveness Program

FM: Ira Wollner, M.D., Chairman
Munther Ajlouni, M.D., Vice Chairman
Human Rights Committee (Institutional Review Board)

RE: Research Proposal, "African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention" (IRB Ref. #)

Date of IRB Approval: October 14, 1998 - October 13, 1999

This is to advise you that the human rights aspects of the above-referenced protocol have been reviewed and approved through the expedited review procedure. This approval is based on Title 45, Section 46.110(b)9 of the HHS Code of Federal Regulations. The protocol will be reviewed by the full Committee as an information item at its next meeting.

The Human Rights Committee and Federal Regulations require that your protocol be reviewed at intervals appropriate to the degree of risk but not less than once per year and that a final report be submitted at the termination of the project. Therefore, either a progress or final report for this proposal should be submitted to the Committee by 9/21/99.

Revisions to the Human Rights protocol must be approved by the Committee prior to implementation. The request to approve an amendment must contain the following information: (1) Name of the project director, (2) name of the research proposal, (3) a description of the amendment and rationale for implementation, (4) a description of how



To: Marvella Ford, Ph.D
October 16, 1998 - Page Two

the amendment will change sample size and/or data analysis, (5) a description of risks as related to the amendment, and (6) a statement as to whether the consent process is changed by the amendment and, if applicable, the revised consent form.

In addition, our IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. This includes but is not limited to advertisements used to recruit subjects.

Moreover, **unexpected events and serious adverse effects** relating to subjects must be reported to the Committee as soon as possible; supplemental information may be appended to the notification form (see enclosure).

Please be sure to keep copies of the signed consent forms on file. One convenient method is to duplicate each signed consent form, leaving the original with the patient's medical record and filing the copy together with all other consent forms for that project.

A copy of the signed and stamped application, indicating approval by the Human Rights Committee, is enclosed for your files.

Forms for progress, final and adverse event reports are available in Research Administration (CFP-1). Please feel free to contact Ms. Julie Washington at ext. 62024 if you have questions regarding these matters.

Enclosures

(f:\users\hrc\)



HENRY FORD HEALTH SCIENCES CENTER

Research Administration

CFP-1
2799 West Grand Boulevard
Detroit, MI 48202-2689
(313) 916-2024 Office
(313) 916-2018 Fax

Thomas Roth, PhD
Director of Research

Lynne M. Pecze, MHA
Administrative Director
of Research

S. David Nathanson, MD
Chair, Care of Experimental
Animals Committee

Ira Wollner, MD
Chair, Human Rights Committee

Leonard Lutter, PhD
Chair, Small Projects
Funding Committee

November 16, 1999

TO: *Marvella Ford, Ph.D*
Center for Medical Treatment Effectiveness Program

FM: Munther Ajlouni, M.D., Chairman
Timothy Roehrs, Ph.D., Vice Chairman
Human Rights Committee (Institutional Review Board)

RE: Research Proposal, *African American Men in the PLCO Trial: Developing and Testing Methods to Increase Retention* (IRB Ref. #:35.10.98)

Period of IRB Approval: November 16, 1999 - November 15, 2000

Thank you for the submission of a progress report for the above-referenced research protocol.

At its meeting on , November 16, 1999 the Human Rights Committee reviewed the progress report and re-approved the human rights aspects of the project.

The Human Rights Committee and Federal Regulations require that each research proposal involving human subjects be reviewed at intervals appropriate to the degree of risk but not less than once per year and that a final report be submitted at the termination of the project. Therefore, either a progress or final report for this proposal should be submitted to the Committee on or before October 12, 2000.



To: *Marvella Ford, Ph.D*
November 16, 1999 - Page Two

Revisions to the Human Rights protocol must be approved by the Committee prior to implementation. The request to approve an amendment must contain the following information: (1) Name of the project director, (2) name of the research proposal, (3) a description of the amendment and rationale for implementation, (4) a description of how the amendment will change sample size and/or data analysis, (5) a description of risks as related to the amendment, and (6) a statement as to whether the consent process is changed by the amendment and, if applicable, the revised consent form.

In addition, our IRB is expected to review all research documents and activities that bear directly on the rights and welfare of participants of research. This includes but is not limited to advertisements used to recruit subjects.

Moreover, **unexpected events and serious adverse effects** relating to subjects must be reported to the Committee as soon as possible; supplemental information may be appended to the notification form (see enclosure).

Please be sure to keep copies of the signed consent forms on file. One convenient method is to duplicate each signed consent form, leaving the original with the patient's medical record and filing the copy together with all other consent forms for that project.

A copy of the signed and stamped application, indicating approval by the Human Rights Committee, is enclosed for your files.

Forms for progress, final and adverse event reports are available in Research Administration. Please contact Ms. Julie Washington at 916-2024 if you have questions or require additional information.

Enc.
(L)

TRANSMITTAL FORM FOR CONTINUATION/FINAL REVIEW OF PROJECT

☐ Continuation Report☐ Final Report☐ Project not started/not funded

Abbreviated Project Title	IRB REF. #
"African American Men in the PLCO Trial: Developing and Testing..."	

Project Director (Name/Degree/Title)
Marvella E. Ford, Ph.D. Senior Bioscientific Staff

Department/Division	Location	Phone Number/Pager
Psychiatry/MEDTEP	One Ford Place, 3E	(313) 874-5433

Co-Investigator (include Name/Degree/Title, Dept/Div, and Phone Number/Pager)
Christine Cole Johnson, Ph.D. Director of Cancer Epidemiology Prevention and Control Josephine Ford Cancer Center, (313) 874-6672

Date of Last IRB Approval	Source of Funding and/or Sponsor	Grant Number
October 21, 1998	Department of Defense	B51004

Name of Grant Proposal (If different from Project Title)

IND/IDE # (If Applicable)	IS THIS A MULTICENTER	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
---------------------------	-----------------------	------------------------------	--

Name of Principal Investigator	Signature	Date
Marvella E. Ford, Ph.D.	<i>Marvella E. Ford</i>	11/04/99
Name of Div Head/Dept Chair/Med Dir	Signature	Date
Glenn Craig Davis, M.D.	<i>Glenn Craig Davis</i>	11/04/99

HRC APPROVAL STAMP

APPROVED

NOV 16 1999

HUMAN RIGHTS COMMITTEE

Protocol Approved By Human Rights Committee (Signature of Chairperson)	Date
<i>[Signature]</i>	11-16-99

HUMAN RIGHTS COMMITTEE (INSTITUTIONAL REVIEW BOARD)
TRANSMITTAL FORM FOR CONTINUATION/FINAL REVIEW OF PROJECT

SUBJECTS IN THE PROJECT	HFH	MULTICENTER (if applicable)
1. WHAT IS THE IRB APPROVED TARGET SAMPLE SIZE?	601 + 20 focus group members	
2. HOW MANY SUBJECTS HAVE BEEN ENROLLED SINCE LAST	601	
3. HOW MANY SUBJECTS HAVE BEEN ENROLLED TO DATE?*	601	
4. HOW MANY SUBJECTS WERE ENROLLED AND THEN DISCONTINUED FROM THE PROJECT SINCE LAST REVIEW?	8 refusals 2 deceased 1 nursing home	
5. IF SUBJECTS WERE DISCONTINUED, PLEASE EXPLAIN WHY. (attach additional sheets if necessary)		

* - Including those discontinued.

PROJECT DESIGN AND PROTOCOL (If answering "Yes" to any question (6-17), attach explanation on separate sheet)		
6. ARE YOU AMENDING THE SAMPLE SIZE?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
7. ARE YOU REVISING THE PURPOSE AND/OR SPECIFIC AIMS?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
8. ARE YOU REVISING INCLUSION/EXCLUSION CRITERIA?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
9. ARE YOU MODIFYING PROCEDURES/INTERVENTIONS/INTERACTIONS?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
10. DO ANY OF THE PROTOCOL REVISIONS REQUIRE SIGNIFICANT RESOURCES OR SERVICES FROM OTHER DEPARTMENTS/AREAS?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
11. DID THE PROJECT SCHEDULE FOR COMPLETION CHANGE?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
12. HAVE YOU ENCOUNTERED ANY LIMITATIONS OR DIFFICULTIES?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

HAVE THERE BEEN ANY ADVERSE OR UNEXPECTED EVENTS NOT PREVIOUSLY REPORTED TO THE IRB		
13. IN HFH SUBJECTS?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
14. IN SUBJECTS ENROLLED IN THE MULTICENTER TRIAL?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

DATA ANALYSIS		
15. WAS AN INTERIM ANALYSIS CARRIED OUT?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
16. ARE PRELIMINARY CONCLUSIONS/FINAL RESULTS AVAILABLE?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

TYPE OF CONSENT (Continuation Reports only)			
<input type="checkbox"/> WRITTEN (ATTACH FORM)	<input checked="" type="checkbox"/> ORAL (ATTACH DESCRIPTION)	<input type="checkbox"/> WAIVED CONSENT	
IS THE CONSENT FORM BEING REVISED AT THIS TIME?			<input type="checkbox"/> YES <input type="checkbox"/> NO

Continuation Application:

6 and 9. The sample size has been amended. Originally, the retention coordinator was only going to contact men assigned to the intervention arm of the present study. Existing PLCO Trial schedulers would make screening appointments for men assigned to the control arm of the study. However, one of the co-investigators pointed out the fact that this could serve to introduce bias into the study. The study protocol has been changed so that the retention coordinator now makes all of the contacts with the all of the men in the study. This protocol change will help to reduce bias that might be associated with style differences in interacting with the study participants. The retention coordinator contacts the men in the intervention arm (n=301) by telephone on a monthly basis and also schedules yearly PLCO Trial cancer screening appointments for the men in the control arm (n=300) of the study.

“African American Men in the PLCO Trial: Developing And Testing
Methods To Increase Retention”

Consultant Meeting Agenda

May 24-25, 1999

May 24, 1999 (Room 3C08, 8:30 a.m. – 5:00 p.m.)

- I. Introductions
- II. Overview of the Department of Defense-funded study “African American Men In The PLCO Trial: Developing And Testing Methods To Increase Retention”
- III. Study Update
- IV. Description of Remaining Work
- V. Review of the Study Timeline
- VI. Development of Focus Group Questions Assessing Attitudes of African American Men Toward Cancer Screening (Review of Similar Work Conducted at Henry Ford Health System with African American Women to Ascertain the Cultural Appropriateness of A Breast Cancer Risk Factor Survey)

May 25, 1999 (Room 1C00, 8:30 a.m. – 2:30 p.m.)

Development of Focus Group Questions (continued)

SCRIPT FOR AT0 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR AT0 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? These screenings include the PSA test, a chest x-ray, a flexible sigmoidoscopy, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for

more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?
IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT0 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, a flexible sigmoidoscopy, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT0 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, a flexible sigmoidoscopy, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT0 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, you have been selected to be in the group of the study that will receive free cancer screening exams. I would like to schedule an appointment so you can take advantage of them.

With this being your first year in the study, your exams will consist of:

- A blood test
- Chest x-ray
- An exam of the prostate
- And a flexible sigmoidoscopy

Since there is preparation involved for your exams, we will send you a packet containing two Fleet enemas and the instructions, a map to the location, and a letter confirming the day, date, time, and location of your appointment.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which of these would be closest to you?

(AFTER DETERMINING THE NEAREST CLINIC)

Because all of the exams are done in the one visit, it will take approximately an hour and a half to two hours for your appointment. Are mornings or afternoons best for you?

Are you available on (day), (date) at (time) at (clinic)?

(AFTER SCHEDULING THE APPOINTMENT), We will be sending you a letter confirming the day, date, and time of your appointment.

I have your address as (address), (street name), (city), (zip code). Is this correct?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, a flexible sigmoidoscopy, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, since this is your first time getting these screenings, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information

you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T0 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. You have been selected to be in the group of the study that will receive free cancer screening exams. I would like to schedule an appointment so you can take advantage of them.

With this being your first year in the study, your exams will consist of:

- A blood test
- Chest x-ray
- An exam of the prostate
- And a flexible sigmoidoscopy

Since there is preparation involved for your exams, we will send you a packet containing two Fleet enemas and the instructions, a map to the location, and a letter confirming the day, date, time, and location of your appointment.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which of these would be closest to you?

(AFTER DETERMINING THE NEAREST CLINIC)

Because all of the exams are done in the one visit, it will take approximately an hour and a half to two hours for your appointment. Are mornings or afternoons best for you?

Are you available on (day), (date) at (time) at (clinic)?

(AFTER SCHEDULING THE APPOINTMENT), We will be sending you a letter confirming the day, date, and time of your appointment.

I have your address as (address), (street name), (city), (zip code). Is this correct?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, a flexible sigmoidoscopy, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, since this is your first time getting these screenings, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T1 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T1 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, I have noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you for this! We are interested in what keeps people involved in projects such as the PLCO Trial. What things were helpful to you in getting your scheduled screenings?

WRITE DOWN THE THINGS THE PARTICIPANT SAYS WERE HELPFUL. Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST, STATE: Mr. _____, I see that you did not get your PSA test when you came to our PLCO clinic last year. Was there something that kept you from getting this exam last year?

(PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their PSA test. Was this something that you experienced? What kept you from getting your PSA test? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THE PSA TEST. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY, STATE: Mr. _____, I see that you did not get your chest x-ray when you came to our PLCO clinic last year. Was there something that kept you from getting this exam last year?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their chest x-ray. Was this something that you experienced? What kept you from getting your chest x-ray? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR CHEST X-RAY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY, STATE: Mr. _____, I see that you did not get your flexible sigmoidoscopy when you came to our PLCO clinic last year. Was there something that kept you from getting this exam last year?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their flexible sigmoidoscopies. Was this something that you experienced? What kept you from getting your flexible sigmoidoscopy? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR FLEXIBLE SIGMOIDOSCOPY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM, STATE: Mr. _____, I see that you did not get your digital rectal exam when you came to our PLCO clinic last year. Was there something that kept you from getting this exam last year?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their digital rectal exam. Was this something that you experienced? What kept you from getting your digital rectal exam? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR DIGITAL RECTAL EXAM. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings last year? (PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. - Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for

more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT1 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings last year? (PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to

help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT1 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic last year. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings last year? (PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to

help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT1 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, I would like to schedule you for this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information

you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T1 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. I would like to schedule this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road , off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

IF SPOUSE/PARTNER IS NOT AVAILABLE, STATE: Please let them know that I called.

IF SPOUSE/PARTNER IS AVAILABLE, STATE: Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T2 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T2 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, I have noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you for this! We are interested in what keeps people involved in projects such as the PLCO Trial. What things were helpful to you in getting your scheduled screenings?

WRITE DOWN THE THINGS THE PARTICIPANT SAYS WERE HELPFUL. Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your PSA test when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- last year and two years ago?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their PSA test. Was this something that you experienced? What kept you from getting your PSA test? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THE PSA TEST. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- last year and two years ago?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their chest x-ray. Was this something that you experienced? What kept you from getting your chest x-ray? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR CHEST X-RAY. STATE: Mr. _____, I understand what

you are saying. I would like to work with you so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your flexible sigmoidoscopy when you came to our PLCO clinic

- two years ago.

Was there something that kept you from getting this exam

- two years ago?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their flexible sigmoidoscopies. Was this something that you experienced? What kept you from getting your flexible sigmoidoscopy? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR FLEXIBLE SIGMOIDOSCOPY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- last year and two years ago?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their digital rectal exam. Was this something that you experienced? What kept you from getting your digital rectal exam? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR DIGITAL RECTAL EXAM. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps

people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings

- last year
- two years ago
- last year and two years ago?

(PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?
IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT2 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PLCO screenings. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT2 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- last year and two years ago.

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PLCO screenings. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT2 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, I would like to schedule you for this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes; transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T2 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. I would like to schedule this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road , off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T3 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T3 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, I have noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you for this! We are interested in what keeps people involved in projects such as the PLCO Trial. What things were helpful to you in getting your scheduled screenings?

WRITE DOWN THE THINGS THE PARTICIPANT SAYS WERE HELPFUL. Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

(PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their PSA test. Was this something that you experienced? What kept you from getting your PSA test? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THE PSA TEST. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago

- two years ago and three years ago
- last year, two years ago, and three years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their chest x-ray. Was this something that you experienced? What kept you from getting your chest x-ray? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR CHEST X-RAY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your flexible sigmoidoscopy when you came to our PLCO clinic

- three years ago.

Was there something that kept you from getting this exam

- three years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their flexible sigmoidoscopies. Was this something that you experienced? What kept you from getting your flexible sigmoidoscopy? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR FLEXIBLE SIGMOIDOSCOPY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago

- two years ago and three years ago
- last year, two years ago, and three years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their digital rectal exam. Was this something that you experienced? What kept you from getting your digital rectal exam? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR DIGITAL RECTAL EXAM. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray (for smokers only), and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT3 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

(PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PLCO screenings. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray (for smokers only), and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT3 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- last year and two years ago
- last year and three years ago
- two years ago and three years ago
- last year, two years ago, and three years ago?

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PLCO screenings. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? These screenings include the PSA test, a chest x-ray (for smokers only), and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT3 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, I would like to schedule you for this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

Have you ever smoked cigarettes, cigars or a pipe on a regular basis for six months or longer? IF NO, DO NOT OFFER OR SCHEDULE THE CHEST X-RAY. IF YES, CONTINUE (OFFER AND SCHEDULE THE CHEST X-RAY.)

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road , off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID, AND INDICATE WHETHER THE PERSON IS A NON-SMOKER OR A SMOKER.)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T3 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. I would like to schedule this year's free cancer screening exams.

First, have you been diagnosed with cancer of the prostate, lung, colon or rectum?
IF NO, CONTINUE. IF YES, CONTINUE BUT DO NOT OFFER OR SCHEDULE AN EXAM OF THAT PLCO ORGAN.

Have you ever smoked cigarettes, cigars or a pipe on a regular basis for six months or longer? IF NO, DO NOT OFFER OR SCHEDULE THE CHEST X-RAY. IF YES, CONTINUE (OFFER AND SCHEDULE THE CHEST X-RAY.)

This year, there is no sigmoidoscopy, so no preparation is involved, but you will receive:

- A blood test
- A Chest x-ray
- And an exam of the prostate

Your appointment will take about an hour and all of the exams will be done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE NON-SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID, AND INDICATE WHETHER THE PERSON IS A NON-SMOKER OR A SMOKER.)

We will send a letter confirming the day, date, time, and the location with a map, and after the exams are done we will send a copy of the results to both you and your physician.

We have your address as (read from the overview). Is that correct? And is your physician Dr. (from the overview) at (address and city)?

Mr. _____, do you have any questions about any of the PLCO screenings you will receive this year? Again, these screenings include the PSA test, a chest x-ray, and a digital rectal exam.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR. Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you. If there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T4 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T4 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, I have noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you for this! We are interested in what keeps people involved in projects such as the PLCO Trial. What things were helpful to you in getting your scheduled screenings?

WRITE DOWN THE THINGS THE PARTICIPANT SAYS WERE HELPFUL. Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their PSA test. Was this something that you experienced? What kept you from getting your PSA test? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THE PSA TEST. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their chest x-ray. Was this something that you experienced? What kept you from getting your

chest x-ray? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR CHEST X-RAY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your flexible sigmoidoscopy when you came to our PLCO clinic

- four years ago.

Was there something that kept you from getting this exam

- four years ago?

PROBE FOR BARRIERS: Sometimes people say that _____ kept them from getting their flexible sigmoidoscopies. Was this something that you experienced? What kept you from getting your flexible sigmoidoscopy? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR FLEXIBLE SIGMOIDOSCOPY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

Was there something that kept you from getting this exam

- last year
- two years ago

- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their digital rectal exam. Was this something that you experienced? What kept you from getting your digital rectal exam? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR DIGITAL RECTAL EXAM. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

(PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screening you will receive this year? Again, this screening will consist of the PSA test.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?
IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT4 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago

- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- four years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

(PROBE FOR BARRIERS.)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screening you will receive **this year**? Again, this screening will consist of the PSA test.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT4 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago

- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- four years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year, two years ago, three years ago, and four years ago
- two years ago, three years ago, and four years ago
- two years ago and three years ago
- two years ago and four years ago
- three years ago and four years ago.

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screening you will receive **this year**? Again, this screening will consist of the PSA test.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?
IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT4 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, I would like to schedule you for this year's free cancer screening exam.

First, I would like to ask . . . Have you been diagnosed with cancer of the prostate, lung, colon or rectum?

IF NO, CONTINUE. IF YES, CONTINUE AND RECORD RESPONSE ON THE OVERVIEW AND ON THE SCHEDULE.

This year we would like to schedule you for a blood test only, and the appointment should be approximately 15 minutes.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE BLOOD AND X-RAY ONLY SLOT, ON THE OVERVIEW, PARTICIPANTS NAME, PHONE # AND PID #.)

We will send a letter confirming the day, date, time, and the location with a map . . .

IF NO PROSTATE OR IF CANCER IS REPORTED OF THE PROSTATE – NO RESULTS ARE MAILED. . . SKIP TO ADDRESS INFORMATION.

. . . and after the exam is done we will send a copy of the results to both you and your physician. We have your physician as Dr. (from the overview) at (address and city). Is that correct?

We have your address as (read from the overview). Is that correct?

Mr. _____, do you have any questions about the PLCO screening you will receive this year? Again, this screening will consist of the PSA test.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you, and if there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T4 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. I would like to schedule this year's free cancer screening exams.

First, I would like to ask . . . Have you been diagnosed with cancer of the prostate, lung, colon or rectum?

IF NO, CONTINUE. IF YES, CONTINUE AND RECORD RESPONSE ON THE OVERVIEW AND ON THE SCHEDULE.

This year we would like to schedule you for a blood test only, and the appointment should be approximately 15 minutes.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road , off of I-75 North.

Which would be the most convenient for you?

At the (designated clinic) I have day, month, and date at time in the morning or time in the afternoon.

Which is the best time for you?

(RECORD IN THE BLOOD AND X-RAY ONLY SLOT, ON THE OVERVIEW, PARTICIPANTS NAME, PHONE # AND PID #.)

We will send a letter confirming the day, date, time, and the location with a map . . .

IF NO PROSTATE OR IF CANCER IS REPORTED OF THE PROSTATE – NO RESULTS ARE MAILED. . . SKIP TO ADDRESS INFORMATION.

. . . and after the exam is done we will send a copy of the results to both you and your physician. We have your physician as Dr. (from the overview) at (address and city). Is that correct?

We have your address as (read from the overview). Is that correct?

Mr. _____, do you have any questions about the PLCO screening you will receive this year? Again, this screening will consist of the PSA test.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you, and if there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T5 MALE

INTRODUCTORY TELEPHONE CALL

Hello, is this Mr. _____? My name is _____. As part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

SCRIPT FOR A T5 MALE

FIRST MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, STATE: Mr. _____, I have noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you for this! We are interested in what keeps people involved in projects such as the PLCO Trial. What things were helpful to you in getting your scheduled screenings?

WRITE DOWN THE THINGS THE PARTICIPANT SAYS WERE HELPFUL. Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

(PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their PSA test. Was this something that you experienced? What kept you from getting your PSA test? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THE PSA TEST. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that ____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago.

Was there something that kept you from getting this exam

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago

- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their chest x-ray. Was this something that you experienced? What kept you from getting your chest x-ray? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR CHEST X-RAY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your flexible sigmoidoscopy when you came to our PLCO clinic

- five years ago.

Was there something that kept you from getting this exam

- five years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their flexible sigmoidoscopies. Was this something that you experienced? What kept you from getting your flexible sigmoidoscopy? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR FLEXIBLE SIGMOIDOSCOPY. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I see that you did not get your digital rectal exam when you came to our PLCO clinic

- two years ago
- three years ago
- four years ago
- five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and five years ago
- three years ago and four years ago
- four years ago and five years ago.

Was there something that kept you from getting this exam

- two years ago
- three years ago
- four years ago
- five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and five years ago
- three years ago and four years ago
- four years ago and five years ago?

PROBE FOR BARRIERS: Sometimes people say that ____ kept them from getting their digital rectal exam. Was this something that you experienced? What kept you from getting your digital rectal exam? WRITE DOWN THE THINGS THE PARTICIPANT SAYS KEPT THEM FROM GETTING THEIR DIGITAL RECTAL EXAM. STATE: Mr. _____, I understand what you are saying. I would like to work with you so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING,

STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. What things kept you from getting your scheduled screenings

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

(PROBE FOR BARRIERS)

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? Again, these screenings will consist of the PSA test and a flexible sigmoidoscopy.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren.

Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?
IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT5 MALE

SECOND MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- five years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- two years ago
- three years ago
- four years ago
- five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and five years ago
- three years ago and four years ago
- four years ago and five years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago

- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PLCO screenings. **RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.**

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? Again, these screenings will consist of the PSA test and the flexible sigmoidoscopy.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you **also** mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today?

IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT5 MALE

THIRD MONTH

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF PARTICIPANT ADHERED TO ALL PREVIOUSLY SCHEDULED SCREENINGS, DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, I noticed that you have had all of your PLCO screenings that you have been scheduled for. I would like to commend you again for this! Mr. _____, we will do our best to make sure that you continue to have a positive experience in the PLCO Trial. GO TO NEXT QUESTION.

IF PARTICIPANT DID NOT ADHERE TO THE PSA TEST DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your PSA test when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your PSA test. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE CHEST X-RAY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest x-ray when you came to our PLCO clinic

- last year
- two years ago
- three years ago
- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your chest x-ray. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE FLEXIBLE SIGMOIDOSCOPY DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your chest flexible sigmoidoscopy when you came to our PLCO clinic

- five years ago.

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your flexible sigmoidoscopy. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO THE DIGITAL RECTAL EXAM DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, when we talked last month, you mentioned _____, that kept you from getting your digital rectal exam when you came to our PLCO clinic

- two years ago
- three years ago
- four years ago
- five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and five years ago
- three years ago and four years ago
- four years ago and five years ago

I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

IF PARTICIPANT DID NOT ADHERE TO ANY OF THE SCHEDULED PLCO SCREENINGS DURING A PREVIOUSLY SCHEDULED PLCO SCREENING, STATE: Mr. _____, I would like to commend you for enrolling in the PLCO Trial! Your participation in this project is very important to us. We are interested in what keeps people from getting their scheduled PLCO screenings. When we talked last month, you mentioned _____, that kept you from getting your PLCO screenings when you came to our PLCO clinic

- last year
- two years ago
- three years ago

- four years ago
- five years ago
- last year, two years ago, three years ago, four years ago, and five years ago
- last year, three years ago, four years ago, and five years ago
- last year, two years ago, three years ago, and four years ago
- last year, two years ago, and five years ago
- last year, two years ago, four years ago, and five years ago
- last year, three years ago, and five years ago
- last year, two years ago, three years ago, and five years ago
- last year, two years ago, and three years ago
- last year, two years ago, and four years ago
- last year, three years ago, and four years ago
- last year, four years ago, and five years ago
- last year and two years ago
- last year and three years ago
- last year and four years ago
- last year and five years ago
- two years ago, three years ago, four years ago, and five years ago
- two years ago, three years ago, and four years ago
- two years ago, three years ago, and five years ago
- two years ago and three years ago
- two years ago, four years ago, and five years ago
- two years ago and four years ago
- two years ago and five years ago
- three years ago, four years ago, and five years ago
- three years ago and four years ago
- three years ago and five years ago
- four years ago and five years ago?

Mr. _____, the information we gain from the PLCO Trial could help future generations of people. In addition, the findings related to prostate cancer may be particularly important to African American men. For these reasons, I would like to work with you to help to make your PLCO screenings as easy for you as possible. I would like to continue our discussion from last month about ways of dealing with these things so that _____ will not keep you from getting your digital rectal exam. RESPOND TO THE BARRIER(S) MENTIONED BY THE PARTICIPANT AND ADDRESS THEM.

Mr. _____, do you have any questions about any of the PLCO screenings you will receive **this year**? Again, these screenings will consist of the PSA test and a flexible sigmoidoscopy.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them

about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR AT5 MALE

ANNUAL SCHEDULING CALL

Hello, is this Mr. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning your friends, children, and grandchildren.

Mr. _____, I would like to schedule you for this year's free cancer screening exam.

First, I would like to ask . . . Have you been diagnosed with cancer of the prostate, lung, colon or rectum?

IF NO – CONTINUE. IF YES, DO NOT SCHEDULE AN EXAM OF THAT PLCO ORGAN.

Have you had a colonoscopy within the last year, or do you plan to have one soon?

IF NO – CONTINUE. IF YES – DO NOT SCHEDULE THE SIGMOIDOSCOPY AND SCHEULE IN BLOOD/X-RAY SLOT.

This year, your appointment will consist of:

- A blood test
- And the flexible sigmoidoscopy

That is the exam of the lower colon and there is preparation involved, so we will send you a packet containing two Fleet enemas and the instructions. We ask that you eat lightly the night before and the morning of your appointment. It will take approximately an hour and a half to two hours to prepare before you leave your house. The appointment will take approximately an hour and a half to two hours because all of the exams are done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which of these is the most convenient for you?

At the (designated clinic) I have day, month and date at time in the morning or time in the afternoon. Which is best for you?

RECORD IN SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME, PHONE # AND PID#.

As I mentioned, we will send the letter confirming the day, date, time and location, a map to the location and the Fleet enemas with the instructions.

Is your address (read from the overview)?

After your exams are done, a copy of the results will be sent to both you and your physician, is that still Dr. (read from the overview), (address)?

Mr. _____, do you have any questions about the PLCO screening you will receive this year? Again, this screening will consist of the PSA test and the flexible sigmoidoscopy.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

After the exams are done and the results are in, both you and the physician you designated will receive a copy of the results.

Thank you, and if there are any questions, either before or after your letter arrives, please don't hesitate to call 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Thank you, and if there are any questions, either before or after your letter arrives, please don't hesitate to call. Our number is 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF PARTICIPANT WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Mr. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Mr. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

ASK: Mr. _____, did you have any other questions or concerns about something in your own life or the lives of your family or friends?

IF PARTICIPANT CAN'T THINK OF ANY MORE QUESTIONS, STATE: It has been nice talking with you today, Mr. _____. If you have any questions, please write them down so that we can talk about them next month. Is your spouse/partner available? IF NOT, STATE: Please let them know that I called and am available to talk with them about any questions or concerns they may have about something in their own lives or the lives of their children, family or friends. I will call again next month.

IF SPOUSE IS AVAILABLE TO TALK, STATE: Hello, is this Ms. _____? My name is _____. How are you? When we talked recently, I let you know that, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I will call your spouse/partner on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, or other health issues. I could even assist you with questions concerning friends, children, and grandchildren. Ms. _____, when we talked last month, you mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF SPOUSE/PARTNER WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. I would like to assist you in finding some answers. While I have you on the telephone, I will check my files again to see whether I have more information on this topic.

IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information. Before we hang up, when we talked last month, you also mentioned that you were concerned about _____. Were you able to find the information you were looking for? IF PARTICIPANT WAS ABLE TO FIND THE INFORMATION, STATE: I'm glad you were able to have your questions answered/your concerns addressed. GO TO NEXT PART OF SCRIPT.

IF SPOUSE/PARTNER WAS NOT ABLE TO FIND THE INFORMATION NEEDED TO ADDRESS THEIR CONCERNS, STATE: I am sorry that your questions were not answered/your concerns were not addressed. IF YOU DON'T HAVE ANY MORE INFORMATION ON THIS TOPIC, STATE: Ms. _____, I will call you back later with additional information.

STATE: Some of the people I've talked to recently have mentioned concerns about their health or the health of their family members and friends, the health care they receive, safety, taxes, transportation, chore services for seniors, child care, education of themselves or their family members, finances and financial assistance, food/nutrition, housing, legal aid, depression, anger, religion, substance abuse, transportation, etc.

Are any of these things (or other things) a concern for you?

WRITE DOWN THE THINGS THE SPOUSE/PARTNER STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

Ms. _____, you mentioned _____. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other concerns you would like to discuss today? (PROBE AGAIN FOR SPECIFIC CONCERNS. WRITE THEM DOWN AND TRY TO FIND THE TELEPHONE NUMBER OF SOMEONE WHO CAN HELP TO ADDRESS THOSE CONCERNS).

IF SPOUSE/PARTNER RAISES ANOTHER ISSUE, WRITE DOWN THE THINGS THE PERSON STATES. TRY TO FIND INFORMATION IN OUR FILES TO HELP THE PERSON WHILE YOU HAVE THEM ON THE TELEPHONE. GIVE THE PERSON THE RELEVANT TELEPHONE NUMBER(S). STATE:

While I have you on the telephone, Ms. _____, let me check my files to find some information about _____. Here it is. There is an agency, _____, that helps to _____. I would like to give you the agency's telephone number so that you can call for more information. Do you have a pen? Here is the telephone number: _____. IF WE HAVE AN IDENTIFIED CONTACT AT THE AGENCY, STATE: When you call, please ask for Mr./Ms. _____.

Do you have any other questions or concerns that you would like to discuss today? IF NOT, STATE: It has been nice talking with you today, Ms. _____. If you have any questions, please write them down so that we can talk about them next month.

SCRIPT FOR A T5 MALE

ANNUAL SCHEDULING CALL WHEN THIS IS THE FIRST CALL EVER MADE WITH THE PARTICIPANT

Hello, is this Mr. _____? My name is _____. I'm calling from the PLCO study at Henry Ford Hospital. This is your final year of the free cancer screening exams and I would like to schedule your appointment, so that you may take advantage of them.

First, I would like to ask . . . Have you been diagnosed with cancer of the prostate, lung, colon or rectum?

IF NO – CONTINUE. IF YES, DO NOT SCHEDULE AN EXAM OF THAT PLCO ORGAN.

Have you had a colonoscopy within the last year, or do you plan to have one soon?

IF NO – CONTINUE. IF YES – DO NOT SCHEDULE THE SIGMOIDOSCOPY AND SCHEULE IN BLOOD/X-RAY SLOT.

This year, your appointment will consist of:

- A blood test
- And the flexible sigmoidoscopy

That is the exam of the lower colon and there is preparation involved, so we will send you a packet containing two Fleet enemas and the instructions. We ask that you eat lightly the night before and the morning of your appointment. It will take approximately an hour and a half to two hours to prepare before you leave your house. The appointment will take approximately an hour and a half to two hours because all of the exams are done in the one visit.

We do these exams at three locations:

- Our Northwest Clinic, at Outer Drive and the Southfield Freeway between 6- and 7-Mile roads,
- Our Fairlane location in Dearborn near the Fairlane shopping mall, and
- Our Downriver Clinic, on Allen Road, off of I-75 North.

Which of these is the most convenient for you?

At the (designated clinic) I have day, month and date at time in the morning or time in the afternoon. Which is best for you?

RECORD IN SIG SLOT AND ON THE OVERVIEW, PARTICIPANT'S NAME,
PHONE # AND PID#.

As I mentioned, we will send the letter confirming the day, date, time and location, a map
to the location and the Fleet enemas with the instructions.

Is your address (read from the overview)?

After your exams are done, a copy of the results will be sent to both you and your
physician, is that still Dr. (read from the overview), (address)?

Mr. _____, do you have any questions about the PLCO screening you will receive this year? Again, this screening will consist of the PSA test and the flexible sigmoidoscopy.

IF PARTICIPANT HAS QUESTIONS ABOUT THE PSA TEST, STATE: The PSA test stands for Prostate Specific Antigen Test. PSA is a substance produced only by the prostate, which is one of the male sex glands. A PSA blood test measures the level of PSA in the bloodstream. A high PSA level is a warning sign that cancer may be present, but it is not a sure sign. On the other hand, a low PSA level does not guarantee a cancer-free prostate. The disease may be in an early stage, with PSA not yet showing up in the blood stream.

IF PARTICIPANT HAS QUESTIONS ABOUT THE CHEST X-RAY, STATE: The chest x-ray involves high-energy radiation used in LOW doses to diagnose diseases.

IF PARTICIPANT HAS QUESTIONS ABOUT THE DRE TEST, STATE: A digital rectal exam (DRE) is a simple procedure in which the doctor inserts a lubricated, gloved finger into the rectum and feels the prostate gland for lumps or hardness.

IF PARTICIPANT HAS QUESTIONS ABOUT THE FLEXIBLE SIGMOIDOSCOPY, STATE: During this procedure, a hollow tube is passed through the anus for inspection of the sigmoid colon. The colon is part of the large intestine.

IF PARTICIPANT WANTS TO KNOW WHAT CANCER IS, STATE: Healthy cells grow, divide, and replace themselves in an orderly way, keeping the body in good repair. When this process goes wrong, the result may be cancer. Cancer actually is the general name given to a group of more than 100 diseases, all causing abnormal growth that destroys body tissue. One result of abnormal growth may be the formation of tumors. Tumors are of two types: benign and malignant. Benign tumors are not cancerous. They do not spread to other parts of the body and they are seldom a threat to life. Malignant tumors are cancerous. They can spread and kill nearby healthy tissues and organs. Cancer cells also can break away from a malignant tumor and metastasize – enter the bloodstream and lymphatic system. The lymphatic system is the interconnected system of spaces and vessels between body tissues and organs by which lymph circulates throughout the body. Lymph is a clear, watery, sometimes faintly yellowish fluid derived from body tissues that contains white blood cells and circulates throughout the lymphatic system. Lymph acts to remove bacteria and certain proteins from the tissues, transport fat from the small intestine, and supply mature lymphocytes to the blood.

ASK THE PARTICIPANT WHETHER HE WOULD LIKE YOU TO WALK HIM THROUGH WHAT WILL HAPPEN AT THE CLINIC, FROM THE TIME HE ENTERS THE DOOR: Mr. _____, would you like me to walk you through what will happen when you arrive at the clinic, from the time you first walk through the door?

IF PARTICIPANT SAYS YES, TELL HIM WHAT WILL HAPPEN.

IF PARTICIPANT SAYS NO, GO TO NEXT PART OF THE SCRIPT.

Thank you, and if there are any questions, either before or after your letter arrives, please don't hesitate to call. Our number is 313-874-6228, and we'll be looking forward to seeing you on (day), (date) at (time) at our (clinic name).

Mr. _____, as part of a research project to help Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial participants receive their cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to your questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist you with questions concerning your friends, children, and grandchildren.

Do you have any questions?

Each call will last at least five minutes. You have the right to end the call at any point. You do not have to be a part of this project. You can decide not to take part at the beginning or you can start and then decide to stop. If you do not participate, you will not be a part of this study. The alternative to not taking part is to not participate in this study.

When I call, if it is close to the time of your annual PLCO screening appointment, I will:

- (1) Schedule the date, time, and location of your next screening appointment and the type of screening you will have next;
- (2) Give you directions to the PLCO screening clinic of your choice;
- (3) Answer your questions about the screening procedures, so that you will know what to expect when you arrive for screening;
- (4) Call you to remind you of your scheduled visit;
- (5) Call you if your appointment is not kept, to help with problems you may have had in keeping the appointment; and
- (6) Help you to find transportation if you need it.

I will make every attempt to provide you with the information or resources that you request.

Information about your participation in this project will be kept confidential and only used for research purposes according to applicable state and federal laws. No personal data such as name, address, or social security number will be used to identify you once the project has ended. If you have questions about your rights as a research participant you may contact Ms. Julie Washington in the Research Office at Henry Ford Hospital at (313) 916-2024.

Whatever you decide, you will not receive a penalty or loss of benefits of any sort based upon your decision. Your decision will not affect the medical care you receive from your usual source or your status in the PLCO Cancer Screening Trial. Thank you very much for your time. I look forward to talking with you in the future.

Mr. _____, is your spouse/partner available now? I would like to introduce myself to them, so that when I call, they will know who I am. I can also assist your spouse/partner with questions they may have as well.

Hello, Ms. _____? My name is _____. I am a Henry Ford Health System employee working on the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. I would like to call your (spouse/partner) on a monthly basis to serve as a resource person, to help to find answers to questions about things such as Social Security, Medicare, health issues or other concerns. I could even assist with questions concerning your friends, children, and grandchildren. I would like to let you know that I would like to serve as a resource person for you as well as Mr. _____. When I call, if you have questions, please let me know, and I will do my best to find answers and solutions. Please feel free to ask me questions about anything.

All right. Have a nice day. I look forward to talking with you soon.

**SCRIPTS USED WHEN A MESSAGE MUST BE LEFT BECAUSE THE
TARGET PERSON IS NOT AVAILABLE**

INTRODUCTORY TELEPHONE CALL

Hello, my name is Vernetta Randolph. As part of a research project to help people in the PLCO Study receive their free cancer screenings, I have been assigned to assist you in receiving your screenings. I would like to call you on a monthly basis to serve as a resource person, to help to find answers to questions your or your family may have about things such as Social Security, Medicare, health issues, Head Start or other concerns.

Each call will last at least five minutes.

I will make every attempt to provide you with the information or resources that you and your family request.

Again, my name is Vernetta Randolph. Please call me at 313-874-6228. Thank you. I look forward to hearing from you soon.

FIRST MONTH FOLLOW-UP

Hello, my name is Vernetta Randolph. When I called you recently, I let you know that as part of a research project to help people in the PLCO Study receive their free cancer screenings, I have been assigned to assist you in receiving your screenings. As I stated, I would like to call you on a monthly basis to serve as a resource person, to help to find answers to questions your or your family may have about things such as Social Security, Medicare, health issues, Head Start or other concerns.

Each call will last at least five minutes.

I will make every attempt to provide you with the information or resources that you and your family request.

Again, my name is Vernetta Randolph. Please call me at 313-874-6228. Thank you. I look forward to hearing from you soon.

SECOND MONTH FOLLOW-UP

Hello, my name is Vernetta Randolph. When I called you recently, I let you know that as part of a research project to help people in the PLCO Study receive their free cancer screenings, I have been assigned to assist you in receiving your screenings. As I stated, I would like to call you on a monthly basis to serve as a resource person, to help to find answers to questions your or your family may have about things such as Social Security, Medicare, health issues, Head Start or other concerns.

Each call will last at least five minutes.

I will make every attempt to provide you with the information or resources that you and your family request.

Again, my name is Vernetta Randolph. Please call me at 313-874-6228. Thank you. I look forward to hearing from you soon.

O:\mford1\public\dod\noreachintro.doc

Telephone Script for Focus Group Participants
African American Males Aged 55+ Years &
NOT in the PLCO Cancer Screening Trial
Focus Group: Tuesday, January 25, 2000 6:00 p.m. - 8:00 p.m.

Telephone Script

Hello, may I please speak to Mr. _____? My name is _____ (interviewer's name), and I am calling on behalf of Henry Ford Health System. I would like to invite you to participate in a meeting. The goal of the meeting is to develop a survey about cancer screening. We are very interested in your attitudes and opinions about this topic. The meeting is called a focus group. We will pay you **\$25 in cash** for your time.

A. Are you aged 55 years or older?

YES

If YES, continue

Or

NO

If NO, then thank them for responding and terminate the call. "Mr. _____, we are looking for men aged 55 years or older. Thank you very much for your time. We will call if another opportunity for you to participate arises".

B. May I confirm that you are an African American male?

YES

If YES, continue

Or

NO

If NO, then thank them for responding and terminate the call. "Mr. _____, our first focus group will be held with African American men. Thank you very much for your time. We will call if another opportunity for you to participate arises".

C. Are you a participant in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial?

NO

If NO, continue

Or

YES

If YES, then thank them for responding and terminate the call. "Mr. _____, our focus group will be held with people who are NOT in the PLCO Cancer Screening Trial. Thank you very much for your time. We will call if another opportunity for you to participate arises".

D. Do you work in the Henry Ford Health System?

NO

If NO, continue

Or

YES

If YES, then thank them for responding and terminate the call. "Mr. _____, our focus group will be held with people who are not Henry Ford Health System employees. Thank you very much for your time. We will call if another opportunity for you to participate arises".

E. Mr. _____, since you are eligible to participate, we would like to invite you to a meeting on **Tuesday, January 25, 2000 from 6:00 p.m. - 8:00 p.m.** The meeting will be held at One Ford Place, located 3 blocks from Henry Ford Hospital. For your attendance we will provide refreshments and pay you **\$25 in cash for the 2-hour meeting**. There is no charge for parking at One Ford Place.

Would you like to attend?

YES

If YES, continue

Or

NO

If NO, then thank them for responding and determine the reasons why (document reasons on the telephone contact sheet provided) and terminate the call. "Mr. _____, thank you very much for your time".

F. The meeting will be recorded (they may use audiotape, videotape and/or a person sitting in the room recording the discussion). This will all be kept confidential. When you attend the meeting you will be asked to read and sign a brief consent form. Would you like to attend the meeting?

YES

If YES, continue

Or

NO

If NO, then thank them for responding and ask for the reason why they do not want to attend (document reason on the telephone contact form) and terminate the call. "Mr. _____, thank you very much for your time".

G. Let me just confirm one more time that you are not participating in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial.

NO

If NO, continue

Or

YES

If YES, then thank them for responding and terminate the call. "Mr. _____, our focus group will be held with people who are NOT in the PLCO Cancer Screening Trial. Thank you very much for your time. We will call if another opportunity for you to participate arises".

H. (If they agree to attend). I will send you a letter confirming your attendance. The letter will include the date, time, meeting room number, a map and also a phone number in the event you have questions or need to cancel. I need to confirm your mailing address (write any changes on the telephone contact form).

Thank you so much for choosing to participate. We look forward to seeing you on **Tuesday, January 25, 2000 at 6:00 p.m.**

Focus Group

Reasons people do not want to participate...

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____

Focus Group

Reasons people do not want to participate...

16. _____
17. _____
18. _____
19. _____
20. _____
21. _____
22. _____
23. _____
24. _____
25. _____
26. _____
27. _____
28. _____
29. _____
30. _____



Center for Medical Treatment Effectiveness Programs
1 Ford Place, Suite 3E, Detroit, MI 48202 (313) 874-1890 Fax (313) 874-6944



Wednesday, January 19, 2000

Dear Mr.:

Thank you for your interest in taking part in a focus group. The goal of the focus group is to develop a survey about cancer screening. We will give you **\$25 in cash** at the end of the two-hour session.

The focus group will take place on Tuesday, January 25, 2000 from **6:00 p.m. - 8:00 p.m.** in **ROOM 3C08** at One Ford Place, the Corporate Headquarters of Henry Ford Health System. Please come at **6:00 p.m. SHARP** or a little earlier.

Enclosed is a map with directions to One Ford Place. Free parking will be provided. Please use the Third Street parking lot and entrance. The parking lot is closely guarded by our security staff.

For your comfort, light refreshments will be served. If you have any questions, please call me at (313) 874-5433. I look forward to meeting you on Tuesday night.

Sincerely,

Marvella E. Ford, Ph.D.

SCRIPT FOR REMINDER CALL FOR FOCUS GROUP
ON TUESDAY, JANUARY 25, 2000
6:00 P.M. - 8:00 P.M.
ROOM 3C08

Hello. This is _____. I am calling on behalf of Dr. Marvella Ford of Henry Ford Health System. Is (person invited to the focus group) at home?

If this is the invited person: I am calling to confirm your attendance at the focus group to develop a survey about cancer screening. It will take place this Tuesday, January 25 (tomorrow night), from 6:00 p.m. - 8:00 p.m. in ROOM 3C08 at 1 Ford Place. Please come at 6:00 p.m. **SHARP** or a little earlier.

You should have received a map providing directions to 1 Ford Place. Free parking will be provided. The parking lot is watched by security guards.

Please enter the building through the Third Street entrance. For your comfort, light refreshments will be served.

Thank you for taking part in the focus group. We will give you **\$25 in cash** at the end of the two-hour meeting.

If the person who signed up is not at home/available to talk: Will you please give (____) the following information?

I am calling to confirm (____)'s attendance at a focus group to develop a survey. It will take place this Tuesday, January 25 (tomorrow night), from 6:00 p.m. - 8:00 p.m. in ROOM 3C08 at 1 Ford Place. Please come at 6:00 p.m. **SHARP** or a little earlier.

(____) should have received a map providing directions to 1 Ford Place. Free parking will be provided. The parking lot is watched by security guards.

(____) should enter through the Third Street entrance. For (____)'s comfort, light refreshments will be served.

I would like to thank (____) for agreeing to take part in the focus group. We will give (____) **\$25 in cash** at the end of the two-hour session.

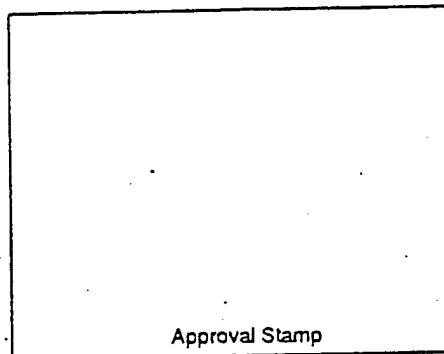
o:\mford1\public\dod\focremin.doc

*Henry Ford Hospital***CONSENT
TO PARTICIPATE IN A RESEARCH STUDY**☐ MAIN☐ WEST BLOOMFIELD☐ FAIRLANE☐ OTHER _____

DATE

MRN

NAME



PROJECT TITLE:

You have been asked to take part in a focus group. The purpose of the focus group is to help develop a survey about cancer screening. Your attitudes and opinions about this topic are valued and appreciated.

The focus group will be videotaped and audiotaped. This will allow the researchers to use the recorded information provided by focus group members to design the survey.

All information related to the focus group will be kept confidential. This means that only researchers and staff who are part of this project will have access to the recorded information.

The videotapes and audiotapes will not be viewed or listened to by anyone who is not directly connected to the project. The information provided by the focus group members will only be used within the institutions represented by the researchers and the research staff.

Henry Ford Hospital

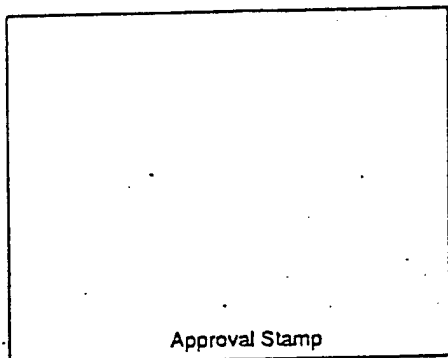
CONSENT
TO PARTICIPATE IN A RESEARCH STUDY

☐ MAIN☐ WEST BLOOMFIELD☐ FAIRLANE☐ OTHER _____

DATE

MRN

NAME



PROJECT TITLE:

There are no known risks associated with involvement in the focus group. You will receive \$25 in cash for your participation. You may not be helped by this study. However, others may be helped by what is learned from this focus group.

Your participation in this focus group is voluntary. You do not have to take part. You can withdraw at any time. If you decide to stop, this will not affect the regular health care you receive at Henry Ford Health system.

This consent form has been reviewed with you. You have read this consent form or it has been read to you. You understand what you have been asked to do. Your questions have been answered and any technical terms you did not understand have been defined for you. You agree to be in this study. You will be given a copy of this consent form.

Signature of Subject_____
Date_____
Printed Name of Subject_____
Date_____
Signature of Witness_____
Date_____
Signature of Investigator_____
Date

303

ACKNOWLEDGMENT OF RECEIPT

I _____ acknowledge receipt of \$25 in cash for my
PRINT NAME IN FULL
participation in the Henry Ford Health System Focus Group on January, 25, 2000.

SIGNATURE

DATE

SOCIAL SECURITY NUMBER _____

Listing of Community Resources
Used in the Retention Study

ADULT DAY CARE

Respite Care
Care For People With Developmental Disabilities

ADULT WELL BEING BUTZEL CENTER

Seniors
Empowerment Zone,
Movies, Picnic, Field Trips
Aarp Materials
Assistance With Cost
Counseling
Health Screenings and Health Lectures
Legal Services
Medicare and Medicaid Assistance
Support Groups
Transportation
Other Activities
Aerobics, Friendship, Games, Needle Craft, Quilting
Business Cards for Seniors
Computer Classes
Food through Focus Hope Food Program
Grandparent Legal Assistance
Prescription Medications
Substance Abuse Prevention Service

AIDS INFORMATION

How AIDS Is Contracted and How It Can Be Prevented

ALZHEIMER'S

Alzheimer's Association of Michigan Detroit Chapter
Educational Program
Helping Hands Respite Care Safe Return Fact Sheet
Kids and Alzheimer's Disease
Library List
Phases of Dementia
Program Summary
Publication Order Form
Support Group
Things Not To Say to Caregiver

AMERICAN DIABETES ASSOCIATION

American Diabetes Association

- Diabetes Information and Action Line
- Diabetes Advocacy
- Diabetes Diagnosis
- Diabetes Facts
- Diabetes Resource Catalog
- First Things First
- Genetics of Diabetes
- Healthy Eating
- Standards of Care
- What is Type I Diabetes?
- What is Type II Diabetes?

AMERICAN CANCER SOCIETY

Community Connection

AMERICAN HEART ASSOCIATION PAMPHLETS

- Cholesterol and Your Heart
- Easy Food Tips For Heart-Health Eating
- Exercise
 - Exercise Diary
- Heart Attack and Stroke: Signals and Action
- High Blood Pressure
- How Can I Monitor My Weight and Blood Pressure?
- How Can I Reduce High Blood Pressure?
- Managing Your Weight
- Now You're Cookin'
- Nutrition
- Nutrition for Fitness
- Nutrition Nibbles
- Sodium and Blood Pressure
- Spring/Summer 1999 Catalog Professional and layperson training solutions
 - 1-800 numbers
- Stroke and Heart Attack
- Walking for a Healthy Heart
- What Are Stroke and TIA?
- What You Should Know About Stroke
- What is Your Risk of Brain Attack?
- What's Your Risk of Heart Attack?
- 1999 Heart and Stroke Statistical Update
- Why Should I Limit Sodium?

AMERICAN LUNG ASSOCIATION

- Facts about Lung Cancer
- Facts in Brief about Lung Disease
- How to Keep Your Lungs Healthy
- The Decision is Yours
- The Lung Cancer Resource Center

AREA AGENCY ON THE AGING

- Detroit Area Agency on Aging 1999 Directory Eldercare Services

CANCER INFORMATION

- American Cancer Society
- Barbara Ann Karmanos Cancer Institute
- Breast Cancer
- Breast Cancer Questions and Answers
- Cancer Facts and Figures for African Americans 1998-1999
- Cancer Facts for Women
- Cancer Facts for Men
- Colon and Rectum Cancer
- Colorectal Cancer
- Guidelines for the Early Detection of Cancer
- Healthfinder Questions and Answers
- National Institutes of Health
- Newsletter: The Health Source
- Prostate Cancer: Facts on Prostate Cancer, Testing For Prostate Cancer
- Resource Guide
- Taking Time Support for People with Cancer and the People Who Care About Them
- What You Need To Know about Cancer of the Colon and Rectum
- What You Need To Know about Lung Cancer

CHILD CARE

- Child Care Centers

COMMUNITY HEALTH AWARENESS

AIDS/HIV

- AIDS Fraud Alert
- AIDS: What Women Need To Know
- Coping with HIV/AIDS
- Community Prescription Service
- Dental Health Matters
- Michigan Jewish AIDS Coalition
- Pocket Reference Guide
- What You Should Know About Videx (didanosine), DDL and HIV
- Case Management
- Certified Church Partner
- Community Awareness Group
- Gay, Lesbian, Bisexual Transgender Community
- Breast Cancer Self Examination

COMMUNITY RESOURCE LIST

Advocacy Services Directory

Child Care Coordinating Council of Detroit/Wayne County Directory of Resources for Children and Family

City of Detroit Directory

Detroit Area Hospital Resource List

Detroit Public Library

Michigan Department of Community Health Maternal and Infant Health

Michigan Senior Resource Directory Community Action Agency Index

State of Michigan Family Independence Agency

COMMUNITY SERVICES AND PROJECTS

Bankruptcy Guide

Chiropractic Guide

Christian Credit Counselors

Cosmetic Surgery

Criminal Law

Dental Guide

Detroit Housing Commission Resident Selection Office Application and Placement Process

Education Guide

General Health

General Legal

Mental Health

MetroMatrix Human Services Local Source

Mortgage Guide

News and Entertainment Updates

Pamphlets and Newsletters

Personal Injury

St. Patrick Senior Center

Social Security and Disability

Women's Health

DOMESTIC VIOLENCE

The Michigan Coalition Against Domestic Violence

Wayne County Neighborhood Legal Services Domestic Violence Clinic

EDUCATION

Directory of Health Education Programs - Henry Ford Hospital

Family Road Programs and Educational Classes - Hutzel Hospital

EMERGENCY ASSISTANCE

Detroit Area Numbers

EMPLOYMENT

Census 2000

National Indian Council on the Aging

FAMILY ROAD PROGRAMS

Hutzel Hospital

FAMILY SUPPORT NETWORK OF MICHIGAN

Family Phone Line

Project Find

The Family Place Mental Health Unit

FOOD AND NUTRITION

Detroit Agriculture Network

Focus Hope

Hunger Action Coalition of Michigan

GRIEF AND BEREAVEMENT

Detroit Area Bereavement Centers

Home Health Agencies Henry Ford Hospital

HABITAT FOR HUMANITY

Habitat for Humanity listing

HEALTH CORE

Health Core Henry Ford Hospital

HEALTH EDUCATION CENTER

American Diabetes Society

Breastfeeding

Cancer Information

Depression

Hearing and Aging

Healthy Food

Heart Attacks

Heat Wave information

Menopause

Michigan Fish

Nutrition for Children

Prostate Cancer

Protecting yourself and your baby from sexually transmitted disease

Substance Abuse

Weight Control

What Do I Need to Know about Hepatitis A, B, and C

Work and Family

HELP FOR YOUTH AND FAMILIES

Baseball Sports Coalition

Covenant House

National Runaway Switchboard

Teen Pregnancy

HOME HEALTH CARE

Care Management

Home Health Care Services (State of Michigan)

HOUSING

Senior Housing

State of Michigan Family Independence Agency

IMMUNIZATION FOR CHILDREN

Child Health Network Immunization Project

Grandparent Immunizing for Tots

Starting Early Wayne County

INFORMATION OF MEDICAL CONDITIONS

Alzheimer's Disease

American Stroke Association

Angina Pectoris

Asthma

Brain Attack Stroke

Cholesterol Disorders

Congestive Heart Failure

Crohn's Disease

Depression

Diabetes Mellitus

Epilepsy

FAQ

Glaucoma

Gout

Green Tree

Hypertension

Report by Center for Clinical Effectiveness

Various other diseases

INSURANCE FOR CHILDREN

Detroit Healthy Start Resource Guide

LEGAL ASSISTANCE

Adult Protective Services Program

Designation of Patient Advocate Form

Domestic Violence Shelter Guide

Durable Power of Attorney for Health Care Henry Ford Hospital

Jewish Home and Aging Services

MedicAlert

The Legal Brief - the Black Women's Lawyers Association of Michigan

MEDICATION ASSISTANCE

Medical Directory
Referral List

MEDICAL INSURANCE

1999 Guide Medicare
AARP
Medical Assistance Detroit
Michigan Medical Assistance Program

MICHIGAN RESOURCE CENTER

1999 Publication Catalog
1999 Videos for Loan

RECIPES

Diabetic
Low Fat

SMOKING/QUITTING

Facts and Tips for Quitting
Involuntary Smoking
Smoking and pregnancy

SENIOR CENTER BUTZEL

SEE Butzel Center
Children's Issues

SOCIAL ACTIVITIES

Exercise
Cultural Happenings Detroit
Detroit Public Library
1999 Wayne County Parks Schedule
1999 Summer Activities Guide

SOCIAL SECURITY

Understanding the Benefits

SUBSTANCE ABUSE

Boniface Intensive Outpatient Day Treatment
Michigan Department of Community Health

TEMPORARY SHELTER

"C-O-T-S"

THE SENIOR ALLIANCE AREA AGENCY ON AGING

Programs
Senior's Guide <http://www.aaalc.org>

TRANSPORTATION

Department of Transportation of Detroit Seniors Services

Health Transportation

Specialized Transportation

UNITED WAY

Community Services

Guide to Health and Human Services

Resources for Community Problem Solving

Surviving Unemployment